EXHIBIT "A"

CV-06-1349

State of Alabama
Unified Judicial System

Form ARCivP-93 Rev. 5/99

COVER SHEET
CIRCUIT COURT - CIVIL CASE
(Not For Domestic Relations Cases)

Case Number: CV [ ][ ][ ][ ][ ][ ]-[ ][ ]

Date of Filing: [ ][ ] Month [ ][ ] Day [ ][ ][ ][ ] Year

Judge Code: [ ][ ][ ][ ]

GENERAL INFORMATION

IN THE CIRCUIT COURT OF Montgomery County, ALABAMA
(Name of County)

Blue Cross and Blue Shield of Alabama et.al
Plaintiff

v.

Pfizer, Inc., et.al
Defendant

First Plaintiff: [X] Business [ ] Individual [ ] Government [ ] Other

First Defendant: [X] Business [ ] Individual [ ] Government [ ] Other

NATURE OF SUIT: Select primary cause of action, by checking box *(check only one)* that best characterizes your action:

TORTS: PERSONAL INJURY
- [ ] WDEA - Wrongful Death
- [ ] TONG - Negligence: General
- [ ] TOMV - Negligence: Motor Vehicle
- [ ] TOWA - Wantonness
- [ ] TOPL - Product Liability/AEMLD
- [ ] TOMM - Malpractice-Medical
- [ ] TOLM - Malpractice-Legal
- [ ] TOOM - Malpractice-Other
- [X] TBFM - Fraud/Bad Faith/Misrepresentation
- [ ] TOXX - Other: _____

TORTS: PROPERTY INJURY
- [ ] TOPE - Personal Property
- [ ] TORE - Real Property

OTHER CIVIL FILINGS
- [ ] ABAN - Abandoned Automobile
- [ ] ACCT - Account & Nonmortgage
- [ ] APAA - Administrative Agency Appeal
- [ ] ADPA - Administrative Procedure Act
- [ ] ANPS - Adults in Need of Protective Services

OTHER CIVIL FILINGS (cont'd)
- [ ] MSXX - Birth/Death Certificate Modification/Bond Forfeiture Appeal/ Enforcement of Agency Subpoena/Petition to Preserve
- [ ] CVRT - Civil Rights
- [ ] COND - Condemnation/Eminent Domain/Right-of-Way
- [ ] CTMP - Contempt of Court
- [ ] CONT - Contract/Ejectment/Writ of Seizure
- [ ] TOCN - Conversion
- [ ] EQND - Equity Non-Damages Actions/Declaratory Judgment/Injunction Election Contest/Quiet Title/Sale For Division
- [ ] CVUD - Eviction Appeal/Unlawful Detainer
- [ ] FORJ - Foreign Judgment
- [ ] FORF - Fruits of Crime Forfeiture
- [ ] MSHC - Habeas Corpus/Extraordinary Writ/Mandamus/Prohibition
- [ ] PFAB - Protection From Abuse
- [ ] FELA - Railroad/Seaman (FELA)
- [ ] RPRO - Real Property
- [ ] WTEG - Will/Trust/Estate/Guardianship/Conservatorship
- [ ] COMP - Workers' Compensation
- [ ] CVXX - Miscellanous Circuit Civil Case

FILED
2006 MAY 12 P 3:49
CIRCUIT COURT OF
MONTGOMERY COUNTY

ORIGIN *(check one)*: F [X] INITIAL FILING; R [ ] REMANDED; A [ ] APPEAL FROM DISTRICT COURT; T [ ] TRANSFERRED FROM OTHER CIRCUIT COURT; O [ ] OTHER: _____

HAS JURY TRIAL BEEN DEMANDED? [X] YES [ ] NO

Note: Checking "Yes" **does not** constitute a demand for a jury trial. (See **Rules 38 and 39, Ala.R.Civ.P**, for procedure)

RELIEF REQUESTED: [X] MONETARY AWARD REQUESTED [ ] NO MONETARY AWARD REQUESTED

ATTORNEY CODE: [ ][ ][ ][ ][ ][ ]

5/12/06
Date

Pamela B. Mata
Signature of Attorney/Party filing this form

MEDIATION REQUESTED: [ ] YES [ ] NO [X] UNDECIDED

State of Alabama Unified Judicial System Form C-34 Rev 6/88	**SUMMONS - CIVIL -**	Case Number CV-06-1349

IN THE Circuit COURT OF Montgomery COUNTY

Plaintiff Blue Cross and Blue Shield of Alabama v. Defendant Pfizer, Inc., et al.

D1

NOTICE TO Pfizer, Inc., c/o The Corporation Company, 2000 Interstate Park Drive, Suite 204, Montgomery, Alabama 36109

THE COMPLAINT WHICH IS ATTACHED TO THIS SUMMONS IS IMPORTANT AND YOU MUST TAKE IMMEDIATE ACTION TO PROTECT YOUR RIGHTS. YOU OR YOUR ATTORNEY ARE REQUIRED TO FILE THE ORIGINAL OF YOUR WRITTEN ANSWER, EITHER ADMITTING OR DENYING EACH ALLEGATION IN THE COMPLAINT WITH THE CLERK OF THIS COURT. A COPY OF YOUR ANSWER MUST BE MAILED OR HAND DELIVERED BY YOU OR YOUR ATTORNEY TO THE PLAINTIFF OR PLAINTIFF'S ATTORNEY Pamela B. Slate, Slate Kennedy LLC WHOSE ADDRESS IS 166 Commerce Street, Suite 350, Montgomer, AL 36104.

THIS ANSWER MUST BE MAILED OR DELIVERED WITHIN 30 DAYS AFTER THIS SUMMONS AND COMPLAINT WERE DELIVERED TO YOU OR A JUDGMENT BY DEFAULT MAY BE ENTERED AGAINST YOU FOR THE MONEY OR OTHER THINGS DEMANDED IN THE COMPLAINT.

TO ANY SHERIFF OR ANY PERSON AUTHORIZED by the Alabama Rules of Civil Procedure:

☐ You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant.

☒ Service by certified mail of this summons is initiated upon the written request of Plaintiff pursuant to the Alabama Rules of Civil Procedure.

Date 05/23/06

Melissa Pittmans
Clerk/Register

FILED
CIRCUIT COURT OF
MONTGOMERY COUNTY
2006 MAY 23 PM 3:52
By:

☒ Certified Mail is hereby requested.

Pamela B Slate
Plaintiff's/Attorney's Signature

U.S. Postal Service
CERTIFIED MAIL RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

OFFICIAL USE

Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$ 7.04

Postmark Here

7000 1530 0002 5002 5138

Sent To Pfizer, Inc
Street, Apt. No.; or PO Box No. 2000 Interstate Park Dr. Ste 204
City, State, ZIP+4 Montg AL 36109-5420

PS Form 3800, May 2000 See Reverse for Instructions

this office on _____ (Date)

of the Summons and Complaint to _____ in _____ County, _____.

_____
Server's Signature

_____
Type of Process Server

State of Alabama Unified Judicial System Form C-34 Rev 6/88	**SUMMONS - CIVIL -**	Case Number CV-06-1349

IN THE Circuit COURT OF Montgomery COUNTY

Plaintiff Blue Cross and Blue Shield of Alabama, et al. **v. Defendant** Pfizer, Inc., et al.

NOTICE TO Warner-Lambert Company LLC, c/0 The Corporation Company D2
2000 Interstate Park Drive, Suite 204, Montgomery, AL 36109

THE COMPLAINT WHICH IS ATTACHED TO THIS SUMMONS IS IMPORTANT AND YOU MUST TAKE IMMEDIATE ACTION TO PROTECT YOUR RIGHTS. YOU OR YOUR ATTORNEY ARE REQUIRED TO FILE THE ORIGINAL OF YOUR WRITTEN ANSWER, EITHER ADMITTING OR DENYING EACH ALLEGATION IN THE COMPLAINT WITH THE CLERK OF THIS COURT. A COPY OF YOUR ANSWER MUST BE MAILED OR HAND DELIVERED BY YOU OR YOUR ATTORNEY TO THE PLAINTIFF OR PLAINTIFF'S ATTORNEY Pamela B. Slate, Slate Kennedy LLC WHOSE ADDRESS IS 166 Commerce Street, Suite 350, Montgomery, AL 36104.

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Date 05/23/06

Melissa Pittman
Clerk/Register

By:

FILED
CIRCUIT COURT OF
MONTGOMERY COUNTY
2006 MAY 12 PM 3:52

☒ Certified Mail is hereby requested.

Pamela B. Slate
Plaintiff's/Attorney's Signature

U.S. Postal Service
CERTIFIED MAIL RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

OFFICIAL USE

Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$ 7.04

Postmark Here

Sent To Wainer-Lambert Co LLC
Street, Apt. No.; or PO Box No. 2000 Interstate Park Drive Ste 204
City, State, ZIP+4 Monte AL 36109

PS Form 3800, May 2000 See Reverse for Instructions

7000 1530 0002 5002 5145

n this office on _____ (Date)

of the Summons and Complaint to _____ in _____ County, _____.

_____
Server's Signature

_____
Type of Process Server

State of Alabama Unified Judicial System Form C-34 Rev 6/88	**SUMMONS - CIVIL -**	Case Number CV-06-1349

IN THE Circuit COURT OF Montgomery COUNTY

Plaintiff Blue Cross and Blue Shield of Alabama, et al. **v. Defendant** Pfizer, Inc., et al.

D3

NOTICE TO Warner-Lambert Company, 235 East 42nd Street, New York, NY 10017

THE COMPLAINT WHICH IS ATTACHED TO THIS SUMMONS IS IMPORTANT AND YOU MUST TAKE IMMEDIATE ACTION TO PROTECT YOUR RIGHTS. YOU OR YOUR ATTORNEY ARE REQUIRED TO FILE THE ORIGINAL OF YOUR WRITTEN ANSWER, EITHER ADMITTING OR DENYING EACH ALLEGATION IN THE COMPLAINT WITH THE CLERK OF THIS COURT. A COPY OF YOUR ANSWER MUST BE MAILED OR HAND DELIVERED BY YOU OR YOUR ATTORNEY TO THE PLAINTIFF OR PLAINTIFF'S ATTORNEY Pamela B. Slate, Slate Kennedy LLC WHOSE ADDRESS IS 166 Commerce Street, Suite 350, Montgomery, AL 36104.

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TO ANY SHERIFF OR ANY PERSON AUTHORIZED by the Alabama Rules of Civil Procedure:

☐ You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant.

☒ Service by certified mail of this summons is initiated upon the written request of Plaintiff pursuant to the Alabama Rules of Civil Procedure.

Date 05/23/06

Melissa Pittman
Clerk/Register

By: [illegible]

FILED
CIRCUIT COURT OF
MONTGOMERY COUNTY
2006 MAY 12 PM 3:53

☒ Certified Mail is hereby requested.

Pamela B Slate
Plaintiff's/Attorney's Signature

U.S. Postal Service
CERTIFIED MAIL RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

O F F I C I A L U S E

Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$ 7.04

Postmark Here

7000 1530 0002 5002 5169

Sent To Warner-Lambert Co.
Street, Apt. No.; or PO Box No. 235 East 42nd Street
City, State, ZIP+4 New York, NY 10017

PS Form 3800, May 2000 See Reverse for Instructions

this office on _____ (Date)

of the Summons and Complaint to _____ in _____ County, _____.

Server's Signature

Type of Process Server

State of Alabama Unified Judicial System Form C-34 Rev 6/88	**SUMMONS - CIVIL -**	Case Number CV-06-1349

IN THE Circuit COURT OF Montgomery COUNTY

Plaintiff Blue Cross and Blue Shield of Alabama, et al. v. Defendant Pfizer, Inc., et al.

D4

NOTICE TO Parke-Davis, a Division of Warner Lambert Company LLC and Warner Lambert Company, 235 East 42nd Street, New York, NY 10017

THE COMPLAINT WHICH IS ATTACHED TO THIS SUMMONS IS IMPORTANT AND YOU MUST TAKE IMMEDIATE ACTION TO PROTECT YOUR RIGHTS. YOU OR YOUR ATTORNEY ARE REQUIRED TO FILE THE ORIGINAL OF YOUR WRITTEN ANSWER, EITHER ADMITTING OR DENYING EACH ALLEGATION IN THE COMPLAINT WITH THE CLERK OF THIS COURT. A COPY OF YOUR ANSWER MUST BE MAILED OR HAND DELIVERED BY YOU OR YOUR ATTORNEY TO THE PLAINTIFF OR PLAINTIFF'S ATTORNEY Pamela B. Slate, Slate Kennedy LLC WHOSE ADDRESS IS 166 Commerce Street, Suite 350, Montgomery, AL 36104.

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TO ANY SHERIFF OR ANY PERSON AUTHORIZED by the Alabama Rules of Civil Procedure:

☐ You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant.

☒ Service by certified mail of this summons is initiated upon the written request of Plaintiff pursuant to the Alabama Rules of Civil Procedure.

Date 05/23/06

Melissa Pittmans
Clerk/Register

By

FILED IN OFFICE
CIRCUIT COURT OF
MONTGOMERY COUNTY
2006 MAY 23 PM 3:52

☒ Certified Mail is hereby requested.

Pamela B Slate
Plaintiff's/Attorney's Signature

U.S. Postal Service
CERTIFIED MAIL RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

OFFICIAL USE

Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$ 7.04

Postmark Here

7000 1530 0002 5002 5121

Sent To Parke-Davis
Street, Apt. No.; or PO Box No. 235 E 42nd Street
City, State, ZIP+4 NY, NY 10017-5703

PS Form 3800, May 2000 See Reverse for Instructions

n this office on _____ (Date)

of the Summons and Complaint to _____ in _____ County,

_____.

_____
Server's Signature

_____
Type of Process Server

State of Alabama Unified Judicial System Form C-34 Rev 6/88	**SUMMONS - CIVIL -**	Case Number CV-06-1349

IN THE Circuit COURT OF Montgomery COUNTY

Plaintiff Blue Cross and Blue Shield of Alabama, et al. **v. Defendant** Pfizer, Inc., et al.

D5

NOTICE TO David B. Longmire, M.D., 13150 Highway 43, Russellville, AL, 35653-4558

THE COMPLAINT WHICH IS ATTACHED TO THIS SUMMONS IS IMPORTANT AND YOU MUST TAKE IMMEDIATE ACTION TO PROTECT YOUR RIGHTS. YOU OR YOUR ATTORNEY ARE REQUIRED TO FILE THE ORIGINAL OF YOUR WRITTEN ANSWER, EITHER ADMITTING OR DENYING EACH ALLEGATION IN THE COMPLAINT WITH THE CLERK OF THIS COURT. A COPY OF YOUR ANSWER MUST BE MAILED OR HAND DELIVERED BY YOU OR YOUR ATTORNEY TO THE PLAINTIFF OR PLAINTIFF'S ATTORNEY Pamela B. Slate, Slate Kennedy, LLC WHOSE ADDRESS IS 166 Commerce Street, Suite 350, Montgomery, AL. 36104

THIS ANSWER MUST BE MAILED OR DELIVERED WITHIN _____ DAYS AFTER THIS SUMMONS AND COMPLAINT WERE DELIVERED TO YOU OR A JUDGMENT BY DEFAULT MAY BE ENTERED AGAINST YOU FOR THE MONEY OR OTHER THINGS DEMANDED IN THE COMPLAINT.

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☐ You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant.

☒ Service by certified mail of this summons is initiated upon the written request of Plaintiff pursuant to the Alabama Rules of Civil Procedure.

FILED
2006 MAY 12 PM 3:53
CIRCUIT COURT OF
MONTGOMERY COUNTY

Date 05/23/06

Melissa Pittengers
Clerk/Register By

☒ Certified Mail is hereby requested.

Pamela B Slate
Plaintiff's/Attorney's Signature

U.S. Postal Service
CERTIFIED MAIL RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

O F F I C I A L U S E

Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$ 10.74

Postmark Here

Sent To David B. Longmire M.D.
Street, Apt. No.; or PO Box No. 13150 Highway 43
City, State, ZIP+4 Russellville AL 35653

PS Form 3800, May 2000 See Reverse for Instructions

7000 1530 0002 2005 5152

n this office on _____ (Date)

of the Summons and Complaint to _____

in _____ County,

_____.

_____
Server's Signature

_____
Type of Process Server

CT CORPORATION
A WoltersKluwer Company

Service of Process Transmittal
05/24/2006
Log Number 511184796

TO: Allen P Waxman
Pfizer Inc.
M.S. 150/02/14, 235 East 42nd Street
New York, NY, 10017-5755

RE: **Process Served in Alabama**

FOR: Warner-Lambert Company LLC (Domestic State: DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Blue Cross & Blue Shield of Alabama, Pltf. vs. Pfizer, Inc., et al. including Warner-Lambert Co., LLC, Dfts.
DOCUMENT(S) SERVED:	Summons, Complaint
COURT/AGENCY:	Montgomery County Circuit Court, AL Case # CV 06 1349
NATURE OF ACTION:	Product Liability Litigation - Drug Litigation - Violation of federal law, fraudulent marketing & sales schemes to promote sales
ON WHOM PROCESS WAS SERVED:	The Corporation Company, Montgomery, AL
DATE AND HOUR OF SERVICE:	By Certified Mail on 05/24/2006 postmarked on 05/12/2006
APPEARANCE OR ANSWER DUE:	30 days
ATTORNEY(S) / SENDER(S):	Pamela B. Slate Slate & Kennedy, LLC 166 Commerce Street Suite 350 Montgomery, AL, 36104
ACTION ITEMS:	SOP Papers with Transmittal, via Fed Ex 2 Day, 790442014148
SIGNED: **ADDRESS:**	The Corporation Company 2000 Interstate Park Drive Suite 204 Montgomery, AL, 36109
TELEPHONE:	334-387-7680

DAILY INTAKE
MAY 30 2006
PFIZER LITIGATION GROUP

State of Alabama Unified Judicial System Form C-34 Rev 6/88	**SUMMONS - CIVIL -**	Case Number CV-06-1349

IN THE Circuit COURT OF Montgomery COUNTY

Plaintiff Blue Cross and Blue Shield of Alabama, et al. **v. Defendant** Pfizer, Inc., et al.

D2

Warner-Lambert Company LLC, c/0 The Corporation Company
2000 Interstate Park Drive, Suite 204, Montgomery, AL 36109

NOTICE TO _____

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☒ Service by certified mail of this summons is initiated upon the written request of Plaintiff pursuant to the Alabama Rules of Civil Procedure.

Date 05/23/06

Melissa Pittman
Clerk/Register

By: _____

FILED
2006 MAY 12 PM 3:56
CIRCUIT COURT OF
MONTGOMERY COUNTY

☒ Certified Mail is hereby requested.

Pamela B. Slate
Plaintiff's/Attorney's Signature

RETURN ON SERVICE:

☐ Return receipt of certified mail received in this office on _____ (Date)

☐ I certify that I personally delivered a copy of the Summons and Complaint to _____ in _____ County, Alabama on _____ (Date)

_____
Date

_____
Server's Signature

_____
Address of Server

_____
Type of Process Server

CT CORPORATION
A WoltersKluwer Company

Service of Process Transmittal
05/24/2006
Log Number 511184787

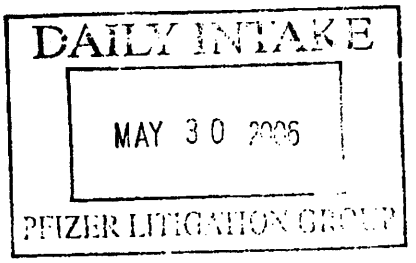
TO: Allen P Waxman
Pfizer Inc.
M.S. 150/02/14, 235 East 42nd Street
New York, NY, 10017-5755

RE: **Process Served in Alabama**

FOR: Pfizer Inc. (Domestic State: DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Blue Cross & Blue Shield of Alabama, Pltf. vs. Pfizer, Inc., et al. Dfts.
DOCUMENT(S) SERVED:	Summons, Complaint
COURT/AGENCY:	Montgomery County Circuit Court, AL Case # CV 06 1349
NATURE OF ACTION:	Product Liability Litigation - Drug Litigation - Violation of federal law, fraudulent marketing & sales schemes to promote sales
ON WHOM PROCESS WAS SERVED:	The Corporation Company, Montgomery, AL
DATE AND HOUR OF SERVICE:	By Certified Mail on 05/24/2006 postmarked on 05/12/2006
APPEARANCE OR ANSWER DUE:	30 days
ATTORNEY(S) / SENDER(S):	Pamela B. Slate Slate & Kennedy, LLC 166 Commerce Street Suite 350 Montgomery, AL, 36104
ACTION ITEMS:	SOP Papers with Transmittal, via Fed Ex 2 Day, 790442014148
SIGNED: **ADDRESS:**	The Corporation Company 2000 Interstate Park Drive Suite 204 Montgomery, AL, 36109
TELEPHONE:	334-387-7680



State of Alabama Unified Judicial System Form C-34 Rev 6/88	**SUMMONS - CIVIL -**	Case Number CV-06-1349

IN THE Circuit COURT OF Montgomery COUNTY

Plaintiff Blue Cross and Blue Shield of Alabama v. Defendant Pfizer, Inc., et al.

D1

NOTICE TO Pfizer, Inc., c/o The Corporation Company, 2000 Interstate Park Drive, Suite 204, Montgomery, Alabama 36109

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☐ You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant.

☒ Service by certified mail of this summons is initiated upon the written request of Plaintiff pursuant to the Alabama Rules of Civil Procedure.

Date 05/23/06

Clerk/Register By:

FILED IN OFFICE CLERK CIRCUIT COURT OF MONTGOMERY COUNTY 2006 MAY 25 PM 3:57

☒ Certified Mail is hereby requested.

Pamela B Slate

Plaintiff's/Attorney's Signature

RETURN ON SERVICE:

☐ Return receipt of certified mail received in this office on _____ (Date)

☐ I certify that I personally delivered a copy of the Summons and Complaint to _____ in _____ County, Alabama on _____ (Date)

Date

Server's Signature

Address of Server

Type of Process Server

DAILY INTAKE
JUN 12 2006
PFIZER LITIGATION GROUP

State of Alabama
Unified Judicial System
Form C-34 Rev 6/88

SUMMONS - CIVIL -

Case Number CV-06-1349

IN THE Circuit COURT OF Montgomery COUNTY

Plaintiff Blue Cross and Blue Shield of Alabama, et al. v. Defendant Pfizer, Inc., et al.

D3

NOTICE TO Warner-Lambert Company, 235 East 42nd Street, New York, NY 10017

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FILED
2006 MAY 12 PM 2:05
CIRCUIT COURT
MONTGOMERY COUNTY

TO ANY SHERIFF OR ANY PERSON AUTHORIZED by the Alabama Rules of Civil Procedure:

☐ You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant.

☒ Service by certified mail of this summons is initiated upon the written request of Plaintiff pursuant to the Alabama Rules of Civil Procedure.

Date 05/23/06

Melissa Pittaway
Clerk/Register

By:

☒ Certified Mail is hereby requested.

Pamela B Slate
Plaintiff's/Attorney's Signature

RETURN ON SERVICE:

☐ Return receipt of certified mail received in this office on _____ (Date)

☐ I certify that I personally delivered a copy of the Summons and Complaint to _____ in _____ County, Alabama on _____ (Date)

_____
Date

_____
Server's Signature

_____
Address of Server

_____
Type of Process Server

DAILY INTAKE
JUN 2 2006
PFIZER LITIGATION GROUP

State of Alabama
Unified Judicial System

Form C-34 Rev 6/88

SUMMONS - CIVIL -

Case Number
Cv-06-1349

IN THE Circuit COURT OF Montgomery COUNTY

Plaintiff Blue Cross and Blue Shield of Alabama, et al. v. Defendant Pfizer, Inc., et al.

D4

NOTICE TO Parke-Davis, a Division of Warner Lambert Company LLC and Warner Lambert Company, 235 East 42nd Street, New York, NY 10017

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FILED
2006 MAY 12 PM 3:57
CIRCUIT COURT
MONTGOMERY COUNTY

Date 05/23/06

Clerk/Register By:

☒ Certified Mail is hereby requested.

Pamela B Slate
Plaintiff's/Attorney's Signature

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☐ Return receipt of certified mail received in this office on _____ (Date)

☐ I certify that I personally delivered a copy of the Summons and Complaint to _____ in _____ County, Alabama on _____ (Date)

Date

Server's Signature

Address of Server

Type of Process Server

IN THE CIRCUIT COURT OF MONTGOMERY COUNTY, ALABAMA

BLUE CROSS AND BLUE SHIELD OF ALABAMA; MUNICIPAL WORKERS COMPENSATION FUND, INC.,

Plaintiffs,

vs.

PFIZER, INC., WARNER-LAMBERT COMPANY LLC; WARNER-LAMBER COMPANY; PARKE-DAVIS, A DIVISION OF WARNER-LAMBERT COMPANY and WARNER-LAMBER COMPANY LLC; DAVID LONGMIRE; and FICTITIOUS DEFENDANTS, the identities of which are unknown to Plaintiffs, and through the exercise of due diligence, cannot be known to Plaintiffs at this time, but who will be added as defendants by amendment as necessary, upon Plaintiffs' identifying them, A, B and C, intending to refer to those persons or entities that are the predecessors or successors in interest to the named Defendants; D-Z, intending to refer to those persons or entities that committed any of the acts and/or omissions of which the named Defendants are alleged herein to have committed; AA-ZZ, intending to refer to those persons or entities that conspired with one or more of the named Defendants, or with any other person or entity to commit the acts and/or omissions alleged herein; AAA-ZZZ, intending to refer to those persons or entities that have committed any acts or omissions that have proximately caused injury and damage to Plaintiffs alleged herein,

Defendants.

CIVIL ACTION NO. Cv-06-1349

COMPLAINT

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CIRCUIT COURT OF
MONTGOMERY COUNTY
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COMPLAINT

COME NOW Plaintiffs, by and through their counsel, and make the following allegations against Defendants, including Fictitious Defendants identified in the style of this Complaint, which style is adopted and incorporated by reference as if fully set forth herein.

I. INTRODUCTION

A. General Information

1. This action is brought by Plaintiffs Blue Cross and Blue Shield of Alabama ("Blue Cross") and Municipal Workers Compensation Fund, Inc. ("MWCF") (collectively hereafter referred to as "Plaintiffs") to recover monies paid by Plaintiffs as a result of Defendants' wrongful scheme to market and sell the drug Neurontin® ("Neurontin") for a variety of uses for which it is not approved, medically necessary or medically effective. Defendant Pfizer, Inc. ("Pfizer") currently markets and sells Neurontin, a drug approved as adjunctive therapy in the treatment of partial seizures for patients with epilepsy. Since May 2002, Neurontin has also been approved for the management of postherpetic neuralgia (pain resulting from shingles or herpes zoster) in adults. Prior to Pfizer's acquisition of Defendant Warner-Lambert Company LLC, the successor to Warner-Lambert Company, (together referred to as "Warner-Lambert") in 2000, Neurontin was marketed and sold by Parke-Davis, a division of Warner-Lambert Company LLC, and previously a division of Warner-Lambert Company ("Parke-Davis").

2. References to Pfizer, Warner-Lambert, or Parke-Davis in this Complaint include all three entities and/or the consolidated entity, and Fictitious Defendants A-ZZZ, unless otherwise specified. References to Defendants or any Defendant include Fictitious

Defendants A-ZZZ. All allegations as to the acts or omissions of any Defendant include the acts or omissions of any agent, employee, representative, or co-conspirator of that Defendant, the acts or omissions of Fictitious Defendants A-ZZZ, and the acts or omissions of any agent, employee, representative, or co-conspirator of Fictitious Defendants A-ZZZ.

3. This action arises out of the wrongful, negligent, fraudulent and unlawful marketing of Neurontin and Defendants' efforts to have doctors prescribe Neurontin for uses for which the drug was neither approved, medically necessary nor effective.

4. Pharmaceutical companies must file a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") for approval to sell a new drug, and are prohibited by the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C.A. §§ 331, *et seq.*, from promoting drugs for uses other than those approved by the FDA. Prescribing drugs for uses other than those approved by the FDA are commonly referred to as "off-label" uses.

5. At all times material hereto, Defendants knew or should have known that Plaintiffs and other entities that pay for prescription drugs for their employees, members, and/or insureds will cover and pay for off-label uses of prescription drugs under certain circumstances. Therefore, to insure the success of their unlawful scheme, Defendants promoted the off-label use of Neurontin so that Plaintiffs would be defrauded or otherwise unlawfully influenced into treating prescriptions of Neurontin as medically necessary and effective, and therefore defrauded or otherwise unlawfully influenced into paying for Neurontin for off-label uses.

6. Strict federal laws and regulations govern the promotion and marketing of drugs for off-label uses. Although Plaintiffs were justified in believing that Defendants would comply with such laws and regulations, Defendants did not comply with such laws and regulations, which are designed to insure that physicians receive accurate, scientifically valid information regarding the effectiveness of a drug for a particular use. From 1994 to the present, Defendants created and implemented a wrongful marketing and sales scheme that dramatically boosted sales of Neurontin and allowed Defendants to reap unlawful and unfair profits at the expense of the Plaintiffs. Using physicians and intermediary marketing entities and firms, Defendants aggressively marketed and sold Neurontin for off-label uses – which ranged from treatment for anxiety to treatment for alcoholism – in spite of a wealth of scientific evidence suggesting that the drug was not medically effective when so used. To carry out this scheme, Defendants employed various methods to make false, misleading and fraudulent representations and statements about Neurontin's effectiveness and medical necessity.

B. The Guilty Plea and Settlement

7. Dr. David Franklin initiated a qui tam action on behalf of the United States against the Parke-Davis division of Warner-Lambert in 1996. He alleged that the knowing promotion of Neurontin for off-label use caused false claims to be presented to the United States for prescription sales that were ineligible for Medicaid reimbursement and also caused the payment of kickbacks in violation of the Medicaid anti-kickback provisions, 31 U.S.C. § 3729.

8. As a result of the filing of the Franklin qui tam lawsuit, the United States Attorney for the District of Massachusetts conducted an investigation and ultimately filed

a criminal case against Warner-Lambert. On May 13, 2004, the company pled guilty to violations of the FDCA. Warner-Lambert was fined $240 million and agreed to cease and desist its pattern of misconduct. The United States Attorney for the District of Massachusetts also opened a civil investigation regarding Defendants' marketing practices with regard to Neurontin.

9. Various State Attorneys General also commenced investigations of off-label marketing practices concerning Neurontin. One group of State Attorneys General and the National Association of Medicaid Fraud Control Units opened civil and criminal investigations against Warner-Lambert for Medicaid fraud. A second group of Attorneys General investigated violations of state consumer protection laws that occurred when Warner-Lambert promoted Neurontin for various off-label uses.

10. The qui tam federal civil investigation and State Attorneys General investigations settled at the same time. As part of an omnibus civil settlement, Warner-Lambert paid $190 million to resolve the civil claims and investigations pending against them.

11. As part of the omnibus civil settlement, Warner-Lambert and the State Attorneys General entered into an Assurance of Voluntary Compliance. The Voluntary Compliance explicitly provided that claims brought by individual consumers and entities were excluded from the omnibus civil settlement.

12. Plaintiffs were diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of their own, they did not receive inquiry notice or learn of the factual basis for their claims in this Complaint against Defendants Pfizer, Warner-Lambert, Parke-Davis, and certain Fictitious Defendants A-ZZZ, or their injuries

suffered therefrom, until after Warner-Lambert's guilty plea and until the cases in which Plaintiffs are putative class members were filed. Plaintiffs did not learn of the factual basis for their claims in this Complaint against Defendant Longmire and certain Fictitious Defendants A-ZZZ, until less than a year preceding the filing of this Complaint. In any event, under the tolling principles applicable in class action cases of which Plaintiffs are putative class members, the statutes of limitation that apply to the claims asserted herein have been tolled such that these claims are timely asserted by Plaintiffs.

II. THE PARTIES

13. Plaintiff Blue Cross is an Alabama nonprofit, nonstock health services corporation, organized and existing under Ala. Code § 10-4-100, et seq. (1975) with its headquarters in Birmingham, Alabama, which provides health care and prescription drug benefits to its members and insureds. Blue Cross has paid or reimbursed eligible beneficiaries' prescription drug benefits for Neurontin for off-label use and was injured by the conduct alleged herein.

13. Plaintiff MWCF is an Alabama corporation headquartered in Montgomery, Alabama. MWCF is a self-funded corporation that provides workers' compensation benefits through its third-party beneficiary, Melenium Risk Managers ("MRM"). MWCF paid or reimbursed eligible fund participants' prescription drug benefits for Neurontin for off-label use and was injured by the conduct alleged herein.

14. Defendant Pfizer is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is principally engaged in the manufacture and sale of pharmaceuticals and is one of the largest pharmaceutical companies in the United States.

15. Defendant Warner-Lambert Company LLC is the successor to Defendant Warner-Lambert Company (together "Warner-Lambert"), and was acquired in June 2000 by Pfizer. This acquisition included Defendant Parke-Davis. Prior to the acquisition, Warner-Lambert was a Delaware corporation that maintained its principal place of business at 201 Tabor Road, Morris Plains, New Jersey. In 1993, Warner-Lambert received FDA approval to market Neurontin in the United States, and did so through its Parke-Davis division. After the acquisition, the marketing of Neurontin continued to be managed at the consolidated companies' Morris Plains, New Jersey location.

16. Defendant David Longmire ("Longmire") is an individual who is, and at all times relevant hereto, was a resident of Russellville, Alabama. As described in detail herein, Defendant Longmire wrongfully marketed, promoted and/or lectured regarding Neurontin and its uses. Longmire is sued herein only as an employee, agent, representative and/or independent contractor of Defendants Pfizer and Warner-Lambert, and is *not* sued for breach of any applicable standard of health care, or for any care provided to, or for the benefit of, any patient.

III. JURISDICTION AND VENUE

17. The amount sought herein exceeds the jurisdictional limits of this Court. This Court has jurisdiction pursuant to Ala. Code § 12-11-30(1) (1975).

18. Venue is proper in this Court pursuant to Ala. Code § 6-3-7(a) & (c) in that (a) a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred outside the State of Alabama, although said events and omissions were intended to and did influence persons within the State of Alabama, (b) the principal offices of Defendants Pfizer and Warner-Lambert are not in Alabama, (c) the principal office of

Plaintiff MWCF is, and at the time of the accrual of the causes of action alleged herein, was in Montgomery County, (d) Defendants Pfizer and Warner-Lambert do, and at the time of the accrual of the causes of action alleged herein, were doing business by agent in Montgomery County, (e) Plaintiffs assert rights to relief arising out of the same transactions or occurrences, (f) the existence of a substantial number of questions of law or material fact common to both Plaintiffs will arise in the action, (g) such questions will predominate over individualized questions pertaining to each Plaintiff, (h) the action can be maintained more efficiently and economically for all parties than if prosecuted separately, and (i) the interest of justice supports the joinder of the parties as plaintiffs in one action. Venue is also proper pursuant to Ala. R. Civ. P. 82(c).

19. Jurisdiction is not proper in any federal court because there is not complete diversity of citizenship among the parties and no claim is made herein that arises under the Constitution, laws, or treaties of the United States. Although Warner-Lambert has pled guilty to violating the FDCA by committing acts alleged herein both directly and/or through its employees, agents and representatives, such as Defendant Longmire, no cause of action is brought herein under the FDCA. Any claims available to Plaintiffs under federal law are specifically disclaimed, although Plaintiffs reserve the right to add federal claims available to them in the event that this action is determined to be removable to a federal court at any time in the future.

IV. FACTUAL ALLEGATIONS[1]

A. Neurontin

20. Defendants Pfizer and Warner-Lambert, through Parke-Davis (collectively referred to as "Parke-Davis") are the manufacturers and distributors of Neurontin, a

[1] Such allegations are upon information or belief.

prescription drug. Neurontin is the brand name of gabapentin. Until 2004, Parke-Davis was the exclusive provider of Neurontin in the United States.

21. In December 1993, the FDA approved Neurontin for "adjunctive therapy" in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. "Adjunctive therapy" means that the drug cannot be prescribed by itself for the treatment of epilepsy -- it is to be used in combination with another "front line" epilepsy drug. The FDA did not find Neurontin to be safe and effective as a "monotherapy" -- a single drug treatment for epilepsy. The FDA approved labeling of Neurontin states that the drug is only effective at doses ranging from 900 to 1800 mg/day. On May 24, 2002, the FDA also approved Neurontin for the management of postherpetic neuralgia, which is pain resulting from nerve damage caused by shingles.

B. Parke-Davis's Deliberate Decision to Avoid FDA Approval and Market Neurontin Off-Label

22. The market potential for Neurontin for its approved use as adjunctive therapy for partial seizures was modest. In May 1994, Parke-Davis estimated that Neurontin's ultimate sales potential was $500 million over the lifetime of the drug, based on Neurontin's narrow use for epilepsy adjunctive therapy.

23. In the late 1980s and early 1990s, before the FDA approved Neurontin for epilepsy adjunctive therapy, Parke-Davis filed several patent applications for Neurontin as a treatment for depression, neurodegenerative disease, mania, bipolar disease and anxiety. Notwithstanding the claims made in the patent applications, Parke-Davis did not seek FDA approval for these indications or start the internal process within Parke-Davis to obtain approval for these uses. Neurontin's short U.S. patent life was likely a major factor in this analysis. The patent was set to expire in a few years, leaving Parke-

Davis with only a small window of exclusivity for this drug during which it could reap monopolistic profits from its sale. After the expiration of the Neurontin patent, Parke-Davis would be forced to share the market for Neurontin with generic drug manufacturers, substantially reducing their profits and their ability to keep Neurontin's retail price high.

24. In October 1994, the Parke-Davis Neurontin Development Team, a group of high-level officials who examined regulatory, clinical research, patents, marketing and manufacturing issues regarding Neurontin, began to consider whether Parke-Davis should attempt to extend Neurontin's use to psychiatric disorders. The principal reason for extending the use was because other anticonvulsants were used for (and FDA-approved for) psychiatric disorders, such as bipolar disorder, panic disorder, post-traumatic stress disorder and possibly personality disorders.

25. Notwithstanding other anti-epileptic drugs being used for psychiatric disorders, Parke-Davis knew or should have known there was no scientific rationale for Neurontin being effective for bipolar disorder, acute mania, social phobia and panic disorder because Neurontin has a different mechanism of action than other anti-epileptics.

26. In January 1995, Parke-Davis's Marketing and Planning department, presented a preliminary market analysis to the Neurontin Development Team regarding Neurontin's potential use for psychiatric indications. Without considering whether the drug was actually effective for such uses, or how Parke-Davis could prove the drug worked for these conditions, the report viewed the market as very favorable for Neurontin. At the same Neurontin Development Team meeting, the possibility of

expanding Neurontin's use for pain syndromes, another market substantially larger than epilepsy, was also discussed.

27. In February 1995, the Parke-Davis New Product Committee ("NPC") informed the Neurontin Development Team that it supported the development of Neurontin for other indications and asked for a formal proposal. John Boris was instructed to prepare market feasibility analyses of new potential indications, including bipolar disorder, generalized anxiety disorder and social phobia, neuropathic pain and migraine prophylaxis.

28. In March 1995, a senior scientist in Parke-Davis's Research Department informed the Neurontin Development Team that it would not be a good use of Parke-Davis resources to obtain regulatory approval for using Neurontin to treat bipolar disorder because of the short patent exclusivity period remaining and because the clinical studies needed to prove that the drug actually worked for this indication would be hard to conduct and expensive. The Development Team, however, was informed that a "publication study will be less expensive and focus on what management organization and clinician want to know." Members of Parke-Davis's Regulatory Department opposed the pursuit of a "publication strategy," stating that seeking FDA approval for bipolar disorder through appropriate clinical studies was the correct way to proceed. That recommendation was not followed.

29. On March 22, 1995, the Parke-Davis Marketing Council, meeting in Lyons, France, recommended that Parke-Davis pursue a "publication strategy" instead of formal regulatory approval with regard to psychiatric indications for Neurontin in the United States because "the patent situation would most likely not allow Parke-Davis to

optimize the investment required to obtain a full indication." Members of the Marketing Council included Tony Wild, the President of Parke-Davis, and senior management.

30. The object of a "publication strategy" was to disseminate information as widely as possible through the world's medical literature. Parke-Davis recognized that publishing Neurontin's studies on off-label uses would increase sales. Parke-Davis estimated that performing clinical trials sufficient to obtain FDA approval would be at least three times the cost of pursuing a publication strategy.

31. In May 1995, a formal Marketing Assessment recommended that Parke-Davis implement a "publication strategy" for various psychiatric indications. The report predicted that the revenues generated by sales for these indications would justify investment in the publication strategy. The report, however, specifically noted a lack of scientific rationale for Neurontin's use for bipolar disorder, since Neurontin has a different mechanism of action than other anti-epileptics. Other Parke-Davis reports had recognized that the scientific rationales for using Neurontin for acute mania, social phobia and panic disorder were essentially the same as the rationale for using Neurontin to treat bipolar disorder, i.e., lacking.

32. In July 1995, the Parke-Davis Marketing and Planning department issued a final Marketing Assessment on Neuropathic Pain and Spasticity. That report recommended that Parke-Davis pursue a publication strategy in the areas of neuropathic pain associated with peripheral nerve damage due to diabetes mellitus, trigeminal neuralgia, postherpetic pain, neuropathic facial pain, and reflex sympathetic dystrophy, disseminating information about such uses through publication and key neurological and pain congresses. Parke-Davis management approved these marketing assessments and

adopted the recommendations regarding the publication strategy. In approving the publication strategy for Neurontin, however, Parke-Davis only intended to publish studies that generated positive results.

33. The New Product Committee also approved the decision to conduct publication studies for Neurontin in migraine prophylaxis but restricted publication to only positive study results. In fact, the negative results of a clinical trial conducted in the 1980s relating to Neurontin and migraine were not published.

34. Thus, by late 1995, senior management at Parke-Davis had committed the company to promoting Neurontin for off-label uses for which it had no intention of ever seeking FDA approval, including bipolar disorder, generalized anxiety disorder, social phobia, migraine, trigeminal neuralgia, postherpetic pain, neuropathic facial pain, and reflex sympathetic dystrophy. No clinical trial suggested that Neurontin was effective for any of these conditions and at least one clinical trial demonstrated that Neurontin was not effective for at least one of these conditions. Moreover, because FDA regulations prohibited Parke-Davis employees from promoting Neurontin for off-label uses, these marketing decisions required Parke-Davis to construct a marketing organization that appeared to be separate and independent from Parke-Davis's existing marketing and sales department, but which was, in fact, controlled by Parke-Davis.

C. Regulation of Marketing Practices and Restrictions on Promotion of Off-Label Uses for Prescription Drugs

35. The FDA closely regulates the marketing and promotion of prescription drugs. Under the FDCA and the regulations promulgated thereunder, all information provided by a drug company about its products, whether on or off-label, whether directed at consumers, physicians, or others, including Plaintiffs, must be fair and balanced. To

be fair and balanced, information about a drug company's products must accurately and fairly present all data relevant to any drug information provided. In practice, this means a drug company must present positive as well as negative information known to a drug company about its products. Drug companies may not present half-truths, omit material information or disclose select information favorable to their position. In order to meet their obligation of providing fair and balanced information, drug companies must make full disclosure.

36. At all times relevant hereto, Parke-Davis's promotion of Neurontin for off-label uses was also closely regulated. The general rule was that drug companies could only promote their products for uses that had been approved by the FDA. Sales personnel could not discuss off-label uses with physicians during sales visits, and off-label uses were not supposed to be discussed in any promotional event sponsored by anyone, including those presented by physicians.

37. The FDA did, however, issue guidelines that allowed drug companies to provide information concerning off-label uses in very limited circumstances. These included:

* Drug companies could provide an unrestricted grant to an accredited independent sponsor of continuing medical education programs, provided the companies did not influence the content of the program. Thus, drug companies could not select the topics to be presented at such programs or approve the speakers or the content to be provided. Only programs that were truly independent of the drug companies were supposed to qualify for this exception.

* Drug companies could provide off-label information to bona-fide medical consultants provided the actual purpose of the consultation was to have the persons retained provide information to the drug companies.

* Drug companies were permitted to communicate off-label information to physicians in response to a bona fide, unsolicited request from a physician, provided such information was specifically responsive to the physician's request.

38. Subsequent to the marketing assessments described above, Parke-Davis's marketing department budgeted millions of dollars to be paid to physicians for "studies" of off-label uses of Neurontin. These "studies" ranged from paying physicians to describe their off-label Neurontin usage to technical writers who would then write case reports under the physicians' names, to substantial subsidies for plans to use Neurontin experimentally on patients. Pursuant to the publication strategy described above, only favorable results would be published and physicians were made to understand that continued funding would only occur if there were favorable results. Many of these studies were not double-blind and most of the studies had little scientific or research value. This initiative, however, resulted in the creation of a wealth of off-label articles Parke-Davis could circulate.

39. Regulation of off-label promotion also restricted the means by which Parke-Davis could publicize information about off-label usage. It could not use its sales force to inform doctors of Neurontin's alleged ability to treat pain or psychiatric conditions, as it normally would when publicizing a new approved pharmaceutical. It had to create parallel marketing structures that appeared independent from Parke-Davis's ordinary promotion forces. Thus, to institute the off-label marketing plan, Parke-Davis had to create a marketing organization that would publicize Neurontin for off-label purposes, but make it appear that Parke-Davis did not have control of the content of the messages being distributed.

40. Parke-Davis's inability to use its usual sales force to promote unapproved uses of Neurontin presented one advantageous opportunity. Parke-Davis was aware that physicians view promotional presentations by drug companies with caution, and are

generally skeptical of representations made by drug company salespersons. However, it also knew that recommendations by fellow practitioners were highly regarded by most physicians and were particularly effective in getting doctors to change prescription behavior. Consequently, Parke-Davis deliberately decided to market Neurontin off- label through "peer-selling."

41. Doctors would be trained to sell Neurontin to other doctors in the guise of educational or professional programs. This marketing strategy, however, could only succeed if it appeared that the doctor-spokespersons were promoting off-label Neurontin because they had independently determined that such treatment was beneficial for their patients, not because they were actually the mouthpieces of a drug company marketing plan. Throughout the off-label promotion campaign Parke-Davis hid their involvement in the promotion of off-label information and misled physicians into believing that the physicians who promoted Neurontin were independent or not otherwise part of the scheme Parke-Davis created to market Neurontin off-label. Longmire was one such physician that promoted Neurontin for off-label purposes on behalf of Parke-Davis.

D. The Off-Label Promotion Scheme

42. Parke-Davis established the Off-Label Promotion Scheme to accomplish two goals that were instrumental to its scheme to market Neurontin for off-label indications. First, it had to create parallel marketing structures that appeared independent from Parke-Davis's ordinary promotion forces to avoid federal regulations concerning off-label promotion. Second, to execute the publication strategy, favorable articles had to be generated and published that appeared to emanate from independent physicians. These two goals were complementary and mutually reinforcing. The production of

favorable publications created a "buzz" regarding Neurontin, while the peer-to-peer marketing and promotion allowed aggressive sales pitches to continue with a veneer of legitimacy. To achieve these goals, at least two methods were used: the Peer Selling Scheme (described below) and the Publication Scheme (described below).

1. The Peer Selling Scheme

43. The Peer Selling Scheme centered on hosting numerous events where doctors trained and/or approved by Parke-Davis would provide favorable information on the off-label use of Neurontin, often under conditions where physicians would be compensated for attending the presentation. Parke-Davis funded hundreds of such events between at least 1996 and 2003. As noted above, Parke-Davis was prohibited from directly producing such events, so it created the Peer Selling Scheme whereby medical marketing firms (the "vendor participants") and several dozen physicians (the "physician participants"), including Longmire, routinely promoted Neurontin to other physicians in venues all across the country.

44. Defendants maintained sufficient control over the events to select and approve the content of the programs and the physician participants that would deliver the off-label message. The physicians who attended these events were deceived into thinking that the events were educational in nature and independent from the control of Defendants .

45. In order to hide the lack of scientific support for the off-label uses promoted by the scheme, and Defendants' direct involvement in Neurontin's off-label promotion, the Defendants employed improper and unlawful sales and marketing practices. These practices included, inter alia: (a) deliberately misrepresenting the safety

and medical efficacy of Neurontin for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical effectiveness or necessity of Neurontin for a variety of off-label uses; (c) deliberately concealing negative findings or the absence of positive findings relating to Neurontin's off-label uses; (d) misrepresenting the credentials and qualifications of certain of Parke-Davis's employees, agents or representatives as specialists, medical researchers, physicians and scientific experts in order to market and sell Neurontin for various off-label uses; (e) wrongfully and illegally compensating physicians for prescribing Neurontin for various off-label uses; (f) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical effectiveness of Neurontin for off-label uses; (i) intentionally misrepresenting and concealing Defendants' role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Neurontin to off-label markets; and (j) intentionally misrepresenting and concealing the financial ties between the Defendants and other participants in the scheme.

46. Defendants' scheme reaped them significant financial gain. From 1995 to 2003, Parke-Davis's revenues from the sale of Neurontin soared from $97.5 million to nearly $2.7 billion. By 2003 90% of all Neurontin prescriptions were for off-label uses. Sales of the drug grew at a rate of 50% per year, fueled primarily by prescriptions for off-label uses. Longmire also received payments from Parke-Davis for his participation in the scheme.

47. All of the participants in the Peer Selling Scheme, including Longmire, aided Parke-Davis in marketing Neurontin for off-label uses and achieving "market

expansion" of these uses. Each of the participants received substantial revenue from Parke-Davis to promote Neurontin off-label. The more successful these marketing events were, the more events there would be in the future and the more fees each of the participants would receive for participating in the events. For these reasons, all of the participants, including Longmire, knowingly and willingly agreed to assist Parke-Davis in the off-label promotion of Neurontin, notwithstanding the fact that such a promotional campaign required the systematic repetition of false and misleading statements to thousands of physicians throughout the United States.

48. Parke-Davis controlled the Peer Selling Scheme. Parke-Davis compensated the other participants, including Longmire, for all of their efforts, and controlled the money flow to the participating vendors and physicians. As described below, on the rare occasions where participants in the Peer-Selling Scheme made statements that failed to support off-label use of Neurontin, Parke-Davis could and would cease the flow of funds to the offending participant. Parke-Davis closely monitored all events to insure the expected representations related to off-label Neurontin were made to physicians attending the events.

49. The Parke-Davis Neurontin Extended Disease Team, a formal team created by the Parke-Davis marketing department that included members of the Parke-Davis marketing department and at least one outside vendor, Cline, Davis & Mann, oversaw the execution of the Peer Selling Scheme. As described herein, Parke-Davis has also controlled the content of the presentations, speeches, promotional events and articles that describe off-label usage of Neurontin.

50. One of Parke-Davis's principal strategies for marketing Neurontin was to target key physicians, preferably within the major teaching hospitals, to serve as "Neurontin champions." These doctors would promote Neurontin to their peers through peer selling programs by (a) touting Neurontin's supposed off-label uses; (b) claiming that Neurontin was being widely used by other physicians for off-label uses; (c) suggesting mechanisms of action that could explain Neurontin's supposed effictivness in off-label areas, even though the mechanism of action in any area was not, and still is not, understood; and (d) claiming that they were privy to the latest clinical data that had not been released yet, but which would support off-label use.

51. To lure physicians to participate in the Peer Selling Scheme, Defendants approached target doctors and informed them of Parke-Davis's interest in funding research opportunities and clinical trials at their institutions. Doctors who were willing to speak favorably about Neurontin could likely receive substantial funds in the form of research grants. Parke-Davis instructed its sales departments to select doctors at the major teaching hospitals to become "Neurontin experts" who would in turn deliver the Neurontin message to other physicians to grow Neurontin sales. This could be done formally to other physicians at marketing events or informally to colleagues within a hospital or medical practice.

52. Having recruited these physicians, Defendants created an explosion in the off-label use of Neurontin by artificially creating the perception that physicians were clinically using Neurontin and investigating its efficacy in off-label uses on their own initiative, and not as a result of the illegal marketing activities. Defendants developed a stable of physicians to create this perception. Parke-Davis paid these physicians to induce

them to write journal articles and letters to the editor that favorably discussed the off-label use of Neurontin. Parke-Davis also paid these physicians (in addition to providing free travel to resorts, free lodging and free meals) to induce them to give talks at medical education seminars, advisory boards, consultants' meetings, speakers bureaus and similar events that favorably discussed the off-label use of Neurontin. The physicians, including Longmire, who accepted these benefits and agreed to promote Neurontin off-label to other doctors were physician participants in the Peer Selling Scheme. The individual physician participants received tens of thousands of dollars to promote Neurontin's off-label uses. Some individual physician participants received more than $100,000.

53. Some physicians participated in the Peer Selling Scheme by publishing favorable journal articles and letters to the editor about off-label use of Neurontin. Parke-Davis paid large sums of money, often in the form of research grants, to the physician participants in order to publish such articles. In some cases, the physician was not required to perform any research or even write the article. Marketing firms were financed by Parke-Davis to ghostwrote articles under the physician participants' names. Physicians merely had to "lend" their names to the articles, in exchange for a payment.

54. Physicians who participated in the Peer Selling Scheme, either as speakers or as authors, entered into a mutually advantageous relationship with Parke-Davis. The more favorable a physician's statements were, the more he or she could expect to receive in the form of speaker fees and research grants.

55. The participating physicians knew that minimal, if any, scientific evidence supported the use of Neurontin for the off-label uses and that the type of clinical evidence that existed was insufficient, under the usual standards in the medical profession, to

represent that Neurontin worked for the unapproved indications. For example, on March 18, 2000, at a meeting in New York City of participating physicians who were planning new "educational" programs regarding off-label Neurontin usage, one psychiatrist admitted to his colleagues:

> (A)lmost everything I'm talking about [reports of successful off-label Neurontin usage] appears in the form of letters to the editor or open case series. The amount of controlled trials, the evidence base for this, is not very good. And there is a sense of feeling awkward -- Elizabeth, this is something we should address -- there's a sense of getting up there and talking about these things [off-label Neurontin usage] when, maybe, at best, there might be one or two controlled trials that support a given use. So, clinical use is running way ahead of what research is giving us. I mean, I can't remember, in psychiatry, anything like this, where there's such extensive use of drugs, without there necessarily being an indication or the data we would consider gold standard. So, one of the questions that I have for you to think about is, can we really say with any certainty that these drugs really work in the way that we're reporting? How confident are you, individually or as a group, that even without the clinical trials, that we can get up in front of clinicians and say, look, trust us that these things do work?

56. These doubts, as well as the limitations of the evidence that supported Neurontin's off-label use and the fact that the type of evidence assembled by Defendants would in any other circumstance be insufficient to permit a recommendation for off-label usage, were facts that had to be reported to the physicians attending events where the participating physicians spoke, in order to avoid the other information they presented from being misleading. However, despite acknowledgements that the limitations of Defendants' evidence had to be addressed, these facts were never disclosed at the events produced through the Peer Selling Scheme or the journal articles created.

2. Publication Scheme

a. Introduction

57. In order to execute their publication strategy, Defendants also needed to generate favorable articles about Neurontin's off-label uses. However, Defendants' control of this strategy had to be kept secret. Articles had to appear as if they emanated from independent physicians who were investigating Neurontin independently. To perform these tasks Defendants established the Publication Scheme to create publications that appeared to be independent.

58. Defendants created the Publication Scheme to hire non-physician technical writers to create the necessary articles and then paid actual specialists to be the articles' "authors." This practice is referred to as "ghostwriting."

59. In order to monitor the status of publications, and in order to coordinate and execute the ghostwriting plan, marketing firms were necessary. The role played by such marketing firms in assisting the Defendants in creating publications was very similar to the role played by marketing firms in the coordination of peer-to-peer marketing events.

b. Misrepresentations and Misleading Statements In Articles Created or Controlled Through the Publication Scheme

60. Publications that Defendants distributed as part of their Publication Scheme intentionally misrepresented Defendants' role in the creation and sponsorship of the publications. Physicians who reviewed these publications were led to believe that the publications were the independent, unbiased research of the authors of the articles. They were not made aware of the fact that Defendants had in fact solicited these articles or that

they had paid significant sums of money in various forms to the physician authors to induce them to make favorable statements about Neurontin.

61. For example, an article widely circulated by Defendants concerning the use of Neurontin in the treatment of Restless Leg Syndrome asserted that the authors Gary A. Mellick and Larry B. Mellick had not and never would receive financial benefit from anyone with an interest in Neurontin. The Mellick brothers had in fact received tens of thousands of dollars for acting as speakers at Defendants' events. Moreover, Gary Mellick never disclosed that he was a consultant with Parke-Davis and was assisting the Company in developing the market for off-label uses of Neurontin.

62. Even in cases where physician-authors drafted the articles themselves, they did so under the direction and control of Defendants. Physicians were promised grants and other gifts if they wrote favorable articles. If a physician attempted to write a negative article, Defendants would attempt to intervene and have a more favorable draft written. If this failed, Defendants would use their best efforts to suppress the article or restrict its dissemination.

63. For example, in 1996, Parke-Davis funded a placebo-controlled clinical trial conducted by Dr. Kenneth Gorson, a doctor at St. Elizabeth's Hospital in Boston, Massachusetts. On August 23, 1997, Gorson submitted a draft of his study to Parke-Davis, accompanied by an abstract. The results of Gorson's study were negative. Gorson's abstract plainly stated that the study did not support Neurontin's use for diabetic peripheral neuropathy. Its conclusion stated that gabapentin "is probably no more effective than placebo in the treatment of painful diabetic neuropathy."

64. Defendants attempted to revise the draft abstract to give it a more favorable conclusion. In January 1998, Parke-Davis circulated a different abstract of the Gorson article which contained the revised conclusion. The conclusion of the abstract circulated by Parke-Davis stated: "Gabapentin may be effective in the treatment of painful diabetic neuropathy. Our results suggest that further studies evaluating higher dosages of gabapentin are warranted." Dr. Gorson refused to adopt this revision.

65. Despite Gorson's refusal to "sugarcoat" his manuscript, Parke-Davis still attempted to control the content of the article. Parke-Davis submitted to the Drugdex Drug Information System ("Drugdex"), a widely used computer database that contains drug information and article citations, a draft of the article which contained language consistent with the false abstract circulated by Parke-Davis but which was not contained in the actual article. Based on this false information, Drugdex published a citation for the Gorson article, which falsely stated: "the authors suggest that higher doses of gabapentin are needed." No such language is in the article. The Drugdex article omits the author's conclusion that gabapentin is "probably ineffective" for the treatment of painful diabetic neuropathy.

66. Defendants took similar steps to misrepresent conclusions regarding Neurontin's effectiveness in the treatment of other unapproved uses.

c. Misrepresentations Through Trials

67. Another method by which Defendants controlled the stream of published information was through its policy of publishing only favorable results of its own internal trials and suppressing results that were unfavorable. In the case of an early trial that failed to show Neurontin's efficacy for migraine, the results were never published. In the

case of a clinical trial that failed to show Neurontin's efficacy for bipolar disorder, the publication of results was delayed until the patent life was set to expire, and even then, Defendants never forwarded a copy of the article to Drugdex.

68. Although Plaintiffs are aware of the policy of suppressing unfavorable studies because of the express terms of the corporate decisions implementing the Publication Strategy, all information regarding negative studies funded by Parke-Davis remains in the sole possession of Defendants and/or members of the Off-Label Promotion Scheme. Without access to records of the studies that were funded and the results of those studies, Plaintiffs cannot identify specific negative findings at this time.

E. Defendants' Use of the Entire Off-Label Promotion Scheme to Make False Statements to Physicians

1. Introduction

69. When presenting off-label information about Neurontin to physicians in response to unsolicited requests for information on unapproved uses, Defendants were required to provide fair and balanced information. Defendants were also required to provide fair and balanced information whenever it engaged in promotional activities. Fair balance was not limited to written materials, but all presentations. Defendants knew that whenever they were required to provide fair and balanced information, federal law and industry standards required them to provide any negative information as well as positive information about their drug products.

70. Within the medical community, in the context of describing properties of approved prescriptions drugs, the terms "effectiveness" and "efficacy" have specific and well understood meanings. Because the FDA will only find a drug product to be effective if the proposed use is supported by well designed, placebo-controlled clinical

trials that establish a causal relationship to a statistically significant degree, a statement that a drug is "effective," or "works," or "has been proven to . . ." is understood to mean that well controlled clinical studies support the use. To make such a statement without such clinical trial proof is misleading. Further, failure to inform physicians that no placebo-controlled clinical trials support a representation of drug efficacy is a violation of a pharmaceutical company's obligation to disclose.

71. Although Defendants have extensively promoted Neurontin for off-label purposes, few placebo-controlled, clinical studies have been conducted on off-label uses of Neurontin. Most of those that have been conducted were negative or inconclusive. For instance, placebo-controlled clinical trials for Neurontin's use for bipolar disorder, unipolar disorder, essential tremor, spasticity, controlled diabetic pain, and panic disorder have all failed to show that Neurontin is effective for those conditions.

72. Any presentation concerning Neurontin's use for indications other than those approved by the FDA that purports to rely on clinical or published evidence must also describe those clinical studies that have found that Neurontin is not effective for off-label uses. Where such information is not provided, any statements about Neurontin's effectiveness for off-label use is false, misleading, distorted, inaccurate, unfair, unbalanced, and omits material facts necessary to be disclosed.

73. Further, federal law and industry standards also prohibited Defendants from misrepresenting scientific evidence that supported (or failed to support) claims that a drug was effective for a specific condition. Thus, anecdotal evidence of a drug's usefulness for a given condition could not be presented as the equivalent of the findings

of a well-designed clinical trial. To fail to comply with these standards violated the Defendants' legal duty to provide accurate and non-misleading information.

74. Defendants routinely and knowingly provided false, inaccurate, misleading, distorted, unfair and unbalanced information about Neurontin's use for unapproved indications. Without discovery, Plaintiffs cannot catalog each misrepresentation and/or misleading statement about Neurontin because Plaintiffs do not possess all transcripts of all meetings. The vast majority of these transcripts are in the possession of the Defendants and/or other members of the Off-Label Promotion Scheme. Plaintiffs have information, however, of misrepresentations, misleading statements and material omissions that were made in specific events as well as misrepresentations, misleading statements and material omissions that were likely made in numerous other events. A description of those false statements, misleading statements and material omissions follow.

2. False and Misleading Statements About Pain

75. At the presentations concerning Neurontin on pain, at least one of the presenters expressly stated or implied that Neurontin was effective for the treatment of pain. A representative statement was made by Longmire. Longmire was a participating physician, agent, employee, representative and/or independent contractor for Defendants at the time of the statement which was made at the Jupiter Beach consultants' meeting in April 1996. At that time, he stated that Neurontin was effective for the treatment of pain. Longmire repeated that statement at a May 1996 Consultants' Meeting at the Ritz Carlton in Boston. Another physician participant, Dr. Steven Schacter made a similar statement at the May 1996 meeting when he stated that "pain specialists are finding that low

dosages of Neurontin are effective." Plaintiffs are aware of comparable statements made by another physician participant, Dr. Bruce Nicholson, in April 1996 at the Jupiter Beach Consultants' Meeting, in May 1996 at the Boston Ritz Carlton Consultants' Meeting and in June 1996 at a Philadephia Consultants' Meeting. Similar statements were made at all events presented by Defendants that discussed Neurontin's use for pain indications.

76. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed. However, with the exception of Neurontin's use for postherpetic neuralgia, no clinical trial evidence exists that supports any claim that Neurontin is effective for the treatment of any other type of pain.

77. In none of the presentations in which Neurontin's use for pain was promoted did the physician participant or any person connected to Defendants acknowledge that there was no clinical trial evidence to support a claim of efficacy. Defendants' failure to disclose this material information made any statement stating that Neurontin was effective for any pain syndrome other than postherpetic neuralgia false and misleading.

78. At every presentation concerning Neurontin's use for pain, neither the participating physicians, nor the participating vendors, nor the Defendants informed the attendee physicians that Defendants had deliberately suppressed negative studies pursuant to the Publication Scheme. Negative studies did in fact exist that indicated or found that Neurontin was not effective for pain, and information regarding these studies was not disclosed.

79. At every presentation concerning Neurontin's use for pain, anecdotal evidence was presented to support Neurontin's use. At none of the presentations, however, was anecdotal evidence presented of Neurontin's failure to treat pain, even though such evidence had been made known to Defendants. Defendants' intentional failure to provide a fair and balanced presentation of the anecdotal information concerning Neurontin's treatment for pain made their presentation false and misleading.

80. Although they were not supposed to discuss off-label indications with physicians, Parke-Davis sales representatives regularly made false statements to doctors about Neurontin's utility in treating pain. The following are representative false statements by the sales force. Similar statements were regularly made by the Parke-Davis sales forces from 1999 through 2004.

* In October 1995, a Parke-Davis sales representative stated that Neurontin had received a "[n]ew indication for chronic pain."

* In December 1995 a Parke-Davis sales representative stated that Neurontin was a "[g]ood anticonvulsant for chronic pain and restless leg syndrome."

* In July 1996, a Parke-Davis sales representative stated that Neurontin was "[e]ffective for many types of chronic pain."

* In December 1996, a Parke-Davis sales representative stated that Neurontin was "[g]ood for back pain; neuropathic pains."

3. Statements Regarding Diabetic Peripheral Neuropathy

81. Although Parke-Davis had no reasonable basis to claim or suggest that Neurontin was effective or could be possibly effective to treat diabetic peripheral neuropathy, at events produced by Parke-Davis, physician participants routinely stated that Neurontin was effective for this condition. A representative statement was made at the Jupiter Beach Consultants Meeting in April 1996, when Dr. Nicholson stated that

diabetic neuropathy patients "will" have their burning sensations relieved. Similar statements were made at all events presented by Defendants that discussed Neurontin's use as a treatment for diabetic peripheral neuropathy.

82. There was no clinical trial support for this assertion. In fact, in 1996 Defendants had requested the Dr. Gorson study discussed at ¶¶ 63-65, *supra*. Dr. Gorson concluded by 1997 that Neurontin was probably ineffective to treat diabetic peripheral neuropathy.

83. Yet, Defendants continued to present numerous events at which Neurontin's use for diabetic peripheral neuropathy was promoted. The physician participants at these presentations failed to describe the results and conclusions of Dr. Gorson's study, and Defendants' representatives at these events also did not provide such information. Defendants' failure to describe negative studies as well as positive studies breached their obligation to provide fair and balanced information and made their representations regarding Neurontin's use for diabetic peripheral neuropathy false and misleading.

4. Representations Regarding Restless Leg Syndrome ("RLS")

84. At events produced by Defendants, physician participants routinely statedthat Neurontin was effective for the treatment of Restless Leg Syndrome ("RLS").

85. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed. However, as discussed below, the clinical studies in existence do not find that Neurontin is effective for the treatment of RLS.

86. In the presentations in which Neurontin's use for RLS was promoted, neither the physician participants nor any person connected to Defendants acknowledged the lack of any clinical trial evidence to support a claim of efficacy. Defendants' failure to disclose this material information made any statement stating that Neurontin was effective for these indications false and misleading.

87. At every presentation concerning Neurontin's use for RLS, neither the participating physicians, the participating vendors, nor the Defendants informed the attendee physicians that Defendants had deliberately suppressed negative studies pursuant to the Publication Scheme. As described below, at least one negative study existed which found that Neurontin was not effective for RLS, and the results of this study were never disclosed when Neurontin's use for RLS was discussed.

88. In 1996, Parke-Davis funded a study conducted by Dr. Bruce Ehrenberg of the New England Medical Center on whether Neurontin was effective for periodic limb movement, a sleep disorder closely related to RLS. Dr. Ehrenberg's study was negative. Less than half the participants who took the drug had improved sleep, and Neurontin had no effect on more than half. Moreover, the drug did not affect any of the participants' limb movements during sleep.

89. Parke-Davis's medical liaisons (discussed in ¶¶ 142-144, *infra*) falsely told physicians that Dr. Ehrenberg's patients had a 90% response rate to Neurontin. In a June 1996 conference call taped by Dr. David Franklin (the qui tam relator), medical liaisons discussed making such assertions routinely. Neither medical liaisons nor physician participants amended their statements to physicians once the results of Dr. Ehrenberg's study were known.

90. Former Parke-Davis officials have admitted that although the results were not favorable, the results of Ehrenberg's study should have been published and made known to clinicians. Indeed, Parke-Davis hired companies to organize this data and to develop a manuscript for him. After the results were received, however, Parke-Davis took no steps to publish an article based on Dr. Ehrenberg's results. Parke-Davis's actions were consistent with the publication strategy, which only intended to publish studies with favorable results. Parke-Davis's policy of only publishing and disclosing the results of favorable studies directly violates its obligation to disclose favorable and unfavorable results.

91. Although they were not supposed to discuss off-label indications with physicians, Parke-Davis sales representatives regularly made false statements to doctors about Neurontin's utility in treating RLS. The following are representative false statements by the sales force. Similar statements were regularly made by the Defendants' sales forces from 1999 through 2004.

* In August 1996, a Parke-Davis sales representative falsely stated that Neurontin was "Effective in controlling postherpetic pain; restless leg syndrome, peripheral neuropathy, migraine headache."

* In December 1996, a Parke-Davis sales representative stated that Neurontin was "Good for restless leg syndrome."

5. Representations Regarding Bipolar Disorder

92. In May 1995, when Parke-Davis created its original marketing assessment for the use of Neurontin to treat bipolar disorder, which is commonly called manic depression, it knew that there was no scientific rationale for Neurontin being an effective agent for treatment. Nonetheless, it planned to promote, and intended the Off-Label Promotion Scheme to promote, Neurontin heavily for bipolar disorder.

93. At events produced by Parke-Davis, physician participants routinely stated that Neurontin was effective for the treatment of bipolar disorder.

94. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed, but as discussed below, clinical studies that were conducted did not find that Neurontin is effective for the treatment of bipolar disorder.

95. At every presentation sponsored by Parke-Davis on the use of Neurontin for bipolar disorder, physicians were not informed that there was no scientific basis for using Neurontin, and Parke-Davis failed to inform the physician attendees of material information that was required to be presented in order for its statements on the use of Neurontin to not be misleading and false and to satisfy its obligation to provide fair and balanced information.

96. By the third quarter of 1997, Parke-Davis knew that the results of its own clinical trial of Neurontin showed that a placebo was more effective than Neurontin in treating bipolar disorder.

97. Although Parke-Davis knew the results of its negative bipolar disorder clinical trial as early as 1997, it did not publish the results until 2000. Nor did it halt the sponsorship of events that promoted Neurontin as an effective treatment of bipolar disorder and other psychiatric conditions.

98. Regardless of the clinical trial results, Parke-Davis continued to make presentations to physician attendees where Neurontin was promoted for use with bipolar disorder patients. In most of these presentations, the attendee physicians were not

informed of the negative clinical trial evidence. For example, Parke-Davis created and sponsored a series of dinner meetings for psychiatrists entitled "Closing the Psychiatry-Neurology Divide: Emerging Uses of Anticonvulsants." This program was presented dozens of times in 1998, including one in St. Petersburg, Florida at Patrick's Bayside Inn. As part of the program, psychiatrists were informed Neurontin was indicated for bipolar disorder, that early evidence suggested that it had anti-depressive and mood-stabilizing effects, and that "data are increasing but currently limited to favorable case reports and open trials." The program did not inform attendees of the unfavorable clinical trials that found that Neurontin was not effective for bipolar disorder and that it was less effective than a placebo.

99. Although they were not supposed to discuss off-label indications with physicians, after placebo-controlled clinical results established that Neurontin was not effective for the treatment of bipolar disorder, Parke Davis's sales force nonetheless regularly made false statements about Neurontin's utility in treating bipolar disorder. Similar statements were regularly made by the Defendants' sales forces at least from 1999 through 2004. Representative statements made to physicians include:

* At a Parke-Davis marketing event in 1997, Parke-Davis falsely stated that Neurontin was "effective" for "bipolar."

* In December 1998, a Parke-Davis sales representative falsely stated to a physician that Neurontin was an "effective treatment of bipolar disorder."

* At a Parke-Davis marketing event in December 1998, Parke-Davis falsely stated that Neurontin was "Effective on bipolar."

* At a Parke-Davis marketing event at the airport Marriott in San Francisco in August 1998, Parke-Davis falsely stated that Neurontin was "Innovative and effective ...for bipolar II."

6. Representations Regarding Social Phobia

100. At events produced by Parke-Davis, participating physicians expressly stated or implied that Neurontin was effective for the treatment of social phobia.

101. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed, but as discussed below, the only clinical study conducted was inconclusive regarding Neurontin's effectiveness for the treatment of social phobia. Prior to its receipt of results of its social phobia clinical trial, Parke-Davis had no reasonable scientific basis for claiming that Neurontin was effective in treating social phobia, because no clinical trial data existed.

102. Even after July 22, 1997, when Parke-Davis received results from its clinical study, it could not state that clinical trial evidence demonstrated Neurontin's efficacy for social phobia. While results were generally favorable on the small sample that completed the study, there were wide inexplicable discrepancies in efficacy between male subjects and female subjects, and between individuals above age 35 compared to those below age 35. The authors admitted that the data was limited, did not conclude that Neurontin was effective, and acknowledged that further studies were necessary to determine whether a dose-response relationship existed. Any statement made by Parke-Davis that claimed or suggested that Neurontin was effective to treat social phobia that did not disclose the limitations of the clinical trial evidence was not fair and balanced and consequently was false and misleading. No such information was provided in the events that promoted treatment of social phobia with Neurontin.

103. At presentations concerning Neurontin's use for social phobia, neither the participating physicians, nor the participating vendors, nor the Defendants informed the attendee physicians that Defendants had deliberately suppressed negative studies pursuant to the Publication Scheme. There were in fact negative studies that indicated or found that Neurontin was not effective for social phobia and information regarding these studies was not disclosed.

104. At presentations concerning Neurontin's use for social phobia, anecdotal evidence was presented to support Neurontin's use. At none of the presentations, however, was anecdotal evidence presented of Neurontin's failure to treat social phobia even though such evidence had been made known to Defendants. Defendants' intentional failure to provide a fair and balanced presentation of the anecdotal information concerning Neurontin's treatment for social phobia made their presentation false and misleading.

7. Representations Regarding Panic Disorder

105. Without favorable results from a well-designed panic disorder clinical trial that established Neurontin's efficacy for that condition, Parke-Davis had no reasonable scientific basis for claiming that Neurontin was effective in treating panic disorder. Nonetheless at events produced by Parke-Davis, physician participants routinely stated that Neurontin was effective for the treatment of panic disorder.

106. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed, but as discussed below, clinical studies that were conducted did not find that Neurontin is effective for the treatment of panic disorder. On

every occasion sponsored by Parke-Davis in which a presentation was given on the use of Neurontin for panic disorder without informing physicians that there was no scientific basis for using Neurontin, Parke-Davis failed to inform the physician attendees of material information that was required to be presented in order for its statements on the use of Neurontin to not be misleading and false and to satisfy its obligation to provide fair and balanced information.

107. In October 1997, Parke-Davis received results of its own clinical trial that found that Neurontin was no more efficacious than placebo in treating panic disorder. Parke-Davis did not publish the results of the negative panic disorder clinical trial until 2000. Regardless of the results of the clinical trial, Parke-Davis continued to sponsor presentations to physician attendees where Neurontin was promoted for use with panic disorder patients. In most of these presentations, the attendee physicians were not informed of the negative clinical trial evidence.

108. At the presentations concerning Neurontin's use for panic disorder, anecdotal evidence was presented to support Neurontin's use. At none of the presentations, however, was anecdotal evidence presented of Neurontin's failure to treat panic disorder patients, even though such evidence had been made known to Defendants. Defendants' intentional failure to provide a fair and balanced presentation of the anecdotal information concerning Neurontin's treatment for panic disorder made their presentations false and misleading.

8. Representations Regarding Monotherapy

109. In numerous presentations produced by Parke-Davis, physician participants asserted that Neurontin was effective monotherapy for the treatment of

epilepsy, despite the fact that it had only been approved by the FDA for adjunctive therapy. As early as November 1995, Parke-Davis knew that clinical trial evidence demonstrated that Neurontin was not an effective monotherapy treatment. Notwithstanding its knowledge of the unsuccessful clinical trials, Parke-Davis continued to make false representations about Neurontin's efficacy as a monotherapy medication and failed to disclose to most attendee physicians the negative clinical trial evidence in its possession.

110. For example, at the Jupiter Beach consultants' meeting in August 1996, Dr. Harden and Dr. LeRoy gave presentations that claimed that Neurontin was effective for monotherapy. Drs. Harden and Leroy misrepresented the results of Clinical Study 945-82, both by claiming that the study did not evidence a failure of Neurontin efficacy and by misrepresenting the lack of a dose response. Furthermore, Dr. Leroy misrepresented that an Eastern European clinical trial had been successful when in fact the double blind codes of the study had not been broken and patient recruitment had not been completed. Notwithstanding that the only long-term clinical trial of Neurontin as monotherapy at the time of the Jupiter Beach meeting demonstrated that Neurontin was not effective for that use, attendees at Jupiter Beach came away with the message that Neurontin was effective. Drs Harden and Leroy could have only received information about the status of these unpublished clinical trials from Parke-Davis.

111. Parke-Davis knew that proof of efficacy for monotherapy required successful completion of two clinical trials demonstrating Neurontin's efficacy. Clinical Study 945-82, a double blind, placebo-controlled study, was designed to be a pivotal study in support of monotherapy. But the results were negative, and failed to demonstrate

that Neurontin was effective in treating seizures at doses up to 2400 mg/day. As early as November 1995, Parke-Davis knew that Clinical Trial 945-82 did not support a monotherapy indication. In addition to failing to establish monotherapy efficacy, Clinical Trial 945-82 also failed to establish a dose response at 600, 1200 and 2400 mg.

112. Parke-Davis also knew that another clinical trial, the Eastern European pilot study 945-177 (an extension of the 945-77 protocol) failed to establish dose differentiation and statistically significant efficacy. Parke-Davis did not intend to publish the results of 945-177, nor did they intend to publish the combined results of 945-77 and 945-177.

113. On September 13, 1996, Parke-Davis submitted a supplemental New Drug Application ("NDA") with the FDA, requesting approval of Neurontin as monotherapy for partial seizures. The FDA determined the application to be non-approvable on August 26, 1997 because of insufficiency of evidence of Neurontin's effectiveness. The FDA noted that Clinical Study 945-82 failed to yield evidence of effectiveness. Parke-Davis did not disclose that its application for monotherapy had been denied.

114. Although Parke-Davis sales representatives were not supposed to make representations about Neurontin's use for monotherapy, their sales representatives routinely made false statements concerning Neurontin's utility as a monotherapy agent. Similar statements were regularly made by the Parke-Davis's sales forces from at least 1999 through 2004. Representative statements made to physicians include:

* In January 1997, a Parke-Davis sales representative falsely stated that Neurontin was "Excellent first line [monotherapy] or add-on prescription for seizures."

* In a 1998 event, Parke-Davis falsely stated that Neurontin "Is effective as monotherapy."

* In October 1995, a Parke-Davis sales representative falsely stated that Neurontin's indicated use was "Soon to be monotherapy."

* In June 1998, after the FDA had already rejected the monotherapy indication and Parke-Davis had abandoned pursuing approval for monotherapy, a Parke-Davis sales representative stated that Neurontin was "moving toward monotherapy indication in seizures."

115. In a Parke-Davis marketing event in 1998, Parke-Davis went so far as to state that Neurontin was "now approved as monotherapy for seizures."

9. Representations Regarding Migraine

116. Parke-Davis knew that there was no pre-clinical rationale that would support the use of Neurontin in migraine prophylaxis.

117. Parke-Davis conducted a 12-week migraine prophylaxis study in Europe during the late 1980's that revealed no statistically significant difference in migraine attack frequency between placebo and 900 mg of Neurontin therapy.

118. In addition to the failed European migraine trial, Parke-Davis knew of several reports of negative results of Neurontin for migraine use, including reports from Dr. Seymour Solomon, Director of the Headache Unit at Montefiore Medical Center; Dr. John Rothrock, Chairman of the Department of Neurology at University of Alabama; Dr. Kenneth Michael Anthony Welch, Professor of Clinical Neurology at the University of Michigan; and Dr. Fred Michael Cutrer, Department of Neurology at Massachusetts General Hospital.

119. Parke-Davis never disclosed the negative results.

120. On May 25, 1996, Parke-Davis held an advisory board meeting to discuss "Gabapentin in the Management of Migraine." Parke-Davis's principal investigator for

Neurontin and migraine chaired the meeting, and there were several other physicians in attendance. There were also several Parke-Davis employees in attendance, including the author of the marketing assessment, John Boris, who was aware of the failed European clinical trial. The purpose of the meeting was to discuss the knowledge of Neurontin's possible utility in the area of migraine and to solicit feedback on the development of clinical trials.

121. At the advisory board meeting, Parke-Davis suppressed any reference to the failed migraine study of the late 1980s. Leslie Magnus-Miller, Parke-Davis's Medical Affairs Director was directly asked, "But do you have any data [relating to Neurontin and migraine]?" Dr. Magnus-Miller responded: "We didn't...No, not really, because we didn't capture headache baseline." Edda Guerrero added: "Unfortunately we did not, not even in monotherapy I think. Right?" John Boris did not correct this misstatement. Parke-Davis also failed to mention that there was "no established preclinical rationale that would support the use of Neurontin in migraine prophylaxis."

122. Thereafter, pursuant to marketing strategies and tactics developed by it, Parke-Davis regularly presented programs or caused programs to be presented in which physician participants touted Neurontin as being effective for the treatment of migraine.

123. Such statements were false and misleading. In these presentations, Parke-Davis failed to inform physician participants of the failed migraine trial or the negative anecdotal evidence it received from its own advisory board physicians. It also failed to inform physicians that there was no established rationale that would support the use of Neurontin for migraine and no clinical trial evidence. Defendants' failure to provide this

information violated their duty of providing fair and balanced information and made any prior statements about Neurontin's use for migraine false and misleading.

124. Although Parke-Davis's sales representatives were not supposed to make representations about Neurontin's use for migraine, their sales representatives routinely made false statements regarding the utility of Neurontin in treating migraine.

10. False Statements About Other Indications

125. Neurontin is prescribed for many additional indications for which there is no scientific support and which are not approved by the FDA. Pursuant to marketing strategies and tactics developed by Parke-Davis, programs were regularly presented in which physician participants touted Neurontin as being effective for other conditions in addition to those described. Such statements were false and misleading, because there was no clinical trial evidence that Neurontin was effective for the treatment of any conditions other than adjunctive therapy for partial seizures and post herpetic neuralgia. In these presentations, Parke-Davis failed to inform physician attendees that there was no established rationale that would support the use of Neurontin for conditions other that adjunctive therapy for partial seizures and postherpetic neuralgia. Defendants' failure to provide this information violated their duty of providing fair and balanced information and made any prior statements about Neurontin's use for conditions other than adjunctive therapy for partial seizures and postherpetic neuralgia false and misleading.

11. False Statements about Dosage

126. Early in its experience in marketing Neurontin, Parke-Davis learned that many physicians did not consider the drug to be efficacious. Parke-Davis attempted to explain this lack of efficacy by trying to convince doctors that they had not given the

patient sufficient medication. At an advisory board meeting, Parke-Davis stated it "therefore went on an aggressive campaign to try to convince the doctors to push the dose of Neurontin up into the 2400 to 3600 mg range."

127. Evidence from clinical studies did not support Parke-Davis's marketing campaign to increase Neurontin dosages beyond the limit approved by the FDA on the grounds of efficacy. Further, Parke-Davis knew of this lack of efficacy. As early as December 30, 1994, Parke-Davis knew that there was a lack of proportionality between the dose of gabapentin administered to subjects and the level absorbed. In other words, increasing the dosage of Neurontin does not necessarily mean that more Neurontin is actually absorbed by the body due to the manner it is excreted and the maximum levels that can accumulate.

128. As of November 14, 1995, Parke-Davis knew that Clinical Trial 945-82 did not show a dose related response. Patients who took 600 mg of Neurontin did not achieve any different results than patients who took 1200mg or 2400 mg. Such results were at odds with Parke-Davis's claim that the larger the dose, the better the effect.

129. Notwithstanding the failure of Clinical Trial 945-82 to exhibit a dose relationship, and notwithstanding the fact that the Core Marketing Team within Parke-Davis intended to initiate a nationwide campaign to convince physicians to increase dosing to at least 2400 mg/day (33% greater than the maximum dosage proven safe and effective), Parke-Davis made the deliberate decision that it would not initiate clinical trials to determine if higher dosages (1800mg to 3600mg) were effective in add-on therapy.

130. A second monotherapy clinical trial confirmed the lack of improved efficacy at higher dosages. In Clinical Trial 945-77, 900 mg/day Neurontin was found to be just as efficacious as Neurontin at 1800 mg/day. Defendants made a deliberate decision not to release the results of clinical trials that did not establish any dose differentiation.

131. Although Parke-Davis was routinely sponsoring programs that recommended that dosages be increased to as high as 4800 mg/day, Parke-Davis knew that it did not have sufficient toxicology data to prove that Neurontin was safe at dosages as high as 3600 mg.

132. During programs presented by Parke-Davis, physician participants routinely stated that dosages above the maximum approved by the FDA increased Neurontin's efficacy. For example, during the migraine advisory board meeting, Dr. Rafferty, a pre-clinical researcher from Parke-Davis, falsely stated the following: "The antiepileptic activity of gabapentin is quite dose dependent. Oh yeah." Parke-Davis was aware that its own clinical trial on Neurontin for epilepsy monotherapy had shown no dose-related difference in efficacy in doses ranging from 600 mg per day to 2400 mg per day. The negative findings of the monotherapy trial were not disclosed to the advisory board members.

133. At the "consultants" meeting in Jupiter Beach in April 1996, Longmire stated that: "most [patients] do better as you raise [the dose] higher." At the same presentation, and in other presentations, such as the Consultants' Meeting at the Boston Ritz Carlton, Longmire also stated that the only reason a patient who was actually taking his medication and not malingering would not receive any benefit from Neurontin was if

he was not receiving a high enough dose. Neither Longmire nor the other Parke-Davis personnel present informed the physicians that Parke-Davis's own clinical trials established that there was no dose relationship.

134. At the Consultants' Meeting at the Boston Ritz- Carlton in May 1996, Longmire made false statements such as: "the problem with Neurontin in terms of real trigeminal neuralgia is that it has to be titrated upward. And when I say 1500 milligrams, that's the target starting dose. There are colleagues in the Huntsville area who, I have people on 5400 with no side effects." This statement was false and misleading for a number of reasons: it implied that Neurontin was effective for trigeminal neuralgia at higher-than-approved doses; it did not disclose side effects reported to Parke-Davis at the higher level; it did not disclose the absence of toxicology data at these levels; it did not disclose there was no clinical data to support Neurontin's efficacy on trigeminal neuralgia; and it failed to disclose Parke-Davis's own clinical trials that questioned the existence of a dose relationship.

135. Notwithstanding the lack of toxicology data and clinical trial data supporting Neurontin's use at higher doses, attendees at Jupiter Beach were led to believe that they should be prescribing Neurontin at higher doses.

136. Parke-Davis applied to the FDA to increase the effective dose range to include 3600 mg/day and to increase the maximum recommended dose to 4800 mg/day. On August 26, 1997, the FDA denied the application because there was no evidence that Neurontin was safe or effective at such doses.

137. Parke-Davis never disclosed that the FDA denied its request to increase the maximum approved dose of Neurontin, that the FDA had determined that Parke-Davis

had not provided sufficient evidence of safety at higher doses, and that there was no clinical trial evidence that Neurontin was more effective at higher doses. Parke-Davis continued to market Neurontin at higher doses without these disclosures.

138. Notwithstanding the FDA's refusal to increase the maximum approved dosage of Neurontin and its finding that no clinical evidence supported Neurontin's efficacy at dosages greater 1800 mg per day, Parke-Davis presented numerous programs where physician participants asserted that Neurontin was effective and safe at dosages above 1800 mg. All such representations were false and misleading. Additionally, at these presentations the physician participants did not disclose the clinical trial evidence that demonstrated that there was no dose response above 1800 mg per day.

139. Defendants' failure to provide this information was a violation of defendants' duties to provide fair and balanced information and made any prior representations about use of Neurontin at dosages greater than 1800 mg false and misleading.

12. Misrepresentation of Promotional Nature of Events

140. As described above, all of the events presented by Parke-Davis were made to appear to the attendee physicians to be bona fide educational events where disinterested leading clinicians shared their knowledge and experience in an educational setting. In fact, these events were peer-selling promotional events designed to convince the attending physicians to prescribe Neurontin. Important facts that would have warned the attendee physicians that they were attending a promotional event for a drug company were concealed. These included the following facts:

* That virtually all of the publications and/or studies that purported to support Neurontin's use for off-label indications were funded by the Defendants;

* That virtually all of the studies that purported to support Neurontin's use for off-label indications had not been initiated by the physicians who were credited as authors, but by the Defendants and other participants in the Off-Label Promotion Scheme pursuant to a corporate marketing plan designed to increase off-label sales;

* That studies existed that found that Neurontin was not effective for off-label uses, but Defendants had deliberately refused to publish or publicize such studies; and

* That the participating doctors who were conducting the peer selling had been paid substantial subsidies to use Neurontin on their patients or in reward for their recommending Neurontin's use for off-label indications.

141. At all events that appeared to be continuing medical education programs, the members of the Off-Label Promotion Scheme described Defendants' contribution as merely the provision of an "unrestricted" grant. For the reasons set forth above, the grants provided by Defendants were not unrestricted but instead were conditioned on Defendants' receipt of a comprehensive program that advocated Neurontin's use for off-label indications and displayed the drug in the most favorable light available. Hiding Defendants' control of the content of the program and misrepresenting its financial support as an "unrestricted" grant were materially false statements that concealed the promotional nature of the programs. Had the attending physicians known the programs were outright promotion they would have viewed the presentations with greater skepticism and doubted the claims of the participating physicians that Neurontin was effective for the off-label indications.

F. Parke-Davis's Use of Medical Liaisons to Promote Off-Label Uses for Neurontin

142. Parke-Davis's normal sales force was not permitted to promote off-label uses of Neurontin to its physician customers. The FDA, however, permitted drug

company representatives to provide balanced, truthful information regarding off-label usage if specifically requested by a physician and if there were no attempt to solicit such information by the drug company. Starting in 1995, Parke-Davis hired medical liaisons that were ostensibly supposed to provide this information to physicians who had requested it. Medical liaisons were also supposed to coordinate funding of studies and clinical trials with interested physicians.

143. In fact, the medical liaison program was part of the same marketing plan and marketing tactics that promoted Neurontin off-label through the Off-Label Promotion Scheme. As another component of the marketing plans produced by the Neurontin Extended Disease Team, Defendants trained medical liaisons to solicit requests for off-label information aggressively from physicians. Having opened this door to a conversation about Neurontin, medical liaisons would then engage in full-scale promotion of Neurontin's off-label uses, including by providing non-scientific, anecdotal information designed to convince physicians that off-label usage of Neurontin was safe and effective. In effect, Parke-Davis used the medical liaisons as a surrogate sales force who marketed Neurontin for off-label uses. Indeed, medical liaisons were selected and promoted based on their ability to sell, and sales training was encouraged.

144. For their presentations to physicians, medical liaisons were trained to provide the same false information described above regarding the efficacy of Neurontin for off-label uses. Similarly, the medical liaisons did not provide all information necessary to make their prior disclosures not false and misleading, including not limited to, failing to inform the physicians with whom they met that there was no scientific

evidence to support Neurontin's use for non-approved indications, failing to disclose negative clinical trial evidence, and failing to disclose negative anecdotal evidence.

G. Parke-Davis's Systematic Payments to Doctors for the Purpose of Increasing Neurontin Prescriptions

145. Customarily, drug companies such as Parke-Davis inform physicians of their new products and those products' uses through office meetings at the physicians' offices by the drug companies' sales force. Defendants could not use this practice to inform physicians of unapproved uses for Neurontin because it could not use its traditional sales force to promote for off-label uses. Defendants had to devise a way to get the doctors to hear their message in other forums. They also had to induce physicians to become part of the Off-Label Promotion Scheme and recommend Neurontin for off-label uses. Parke-Davis elected to pay kickbacks and otherwise provide participant and attendee physicians with items of substantial value to induce them to listen to the off-label marketing pitch, to prescribe Neurontin, and to recommend Neurontin to other physicians. Parke-Davis also paid kickbacks and provided other items of value to reward physicians for having prescribed Neurontin. Parke-Davis made thousands of payments for these purposes in violation of kickback and bribery laws. Many of these payments were technically made by the vendor participants, but Parke-Davis provided the funds for all of the payments, knowing that these payments would be made to induce physicians to change their prescribing behavior regardless of their fiduciary duties to their patients, their practices and their treatment networks.

146. Plaintiffs have already described how Parke-Davis paid physician participants, such as Defendant Longmire, substantial fees (as well as extensive travel benefits) for agreeing to engage in peer-to-peer selling on behalf of off-label Neurontin.

Plaintiffs have also described how Defendants induced physicians to use Neurontin on their patients or rewarded physicians for having used Neurontin on their patients by paying them for "studies" that had minimal, if any, scientific value or paying them to use their names on ghost written articles. Such payments and provision of items of value were expressly performed for the purpose of influencing the recipients' conduct.

147. Additionally, Parke-Davis provided payments and items of substantial value to physicians that were the targets of the Off-Label Promotion Scheme. Parke-Davis routinely provided substantial items of value to these physicians to attend events at which off-label uses of Neurontin were being promoted. The following describes various ways Parke-Davis funneled bribes to physicians.

1. Consultants' Meetings

148. Parke-Davis regularly convened "consultants" meetings as a method for funneling cash and other benefits to physicians in exchange for hearing extensive presentations on the use of Neurontin for off-label purposes. There was no attempt at these meetings, which were often held in luxury resorts, to conform to the requirements of a Continuing Medical Education ("CME") meeting. Instead, Defendants and the vendor participants structured the meeting as if the attendee doctors had been retained by Parke-Davis to advise the company on a strategic issue. The "consultants" were not chosen to attend based on particular skills or expertise the physician possessed, but because of the potential to write Neurontin prescriptions. Only "high decile," i.e., high prescribing, physicians were selected for these meetings.

149. The vendor participants arranged for the doctors' transportation, lodging and entertainment and sometimes (but not always) had the doctors sign sham consulting

agreements. At these meetings Parke-Davis's agents or employees or doctor participants, such as Defendant Longmire, would give the "consultants" substantial presentations relating to Neurontin, particularly its use for unapproved indications. At some conferences, the vendor participant or Defendants intentionally posed questions to the speakers about off-label use to insure the attendees were exposed to such information.

150. The consultants' meetings were not held, and the "consultants" were not paid, for the purpose of providing Parke-Davis with expert, independent advice. Defendants in many cases did not even record the "advice" provided by its "consultants," and what little advice was collected was never acted upon or reviewed. Rather, Parke-Davis routinely analyzed whether consultants' meetings successfully influenced physicians' prescription writing practices. At some meetings, the "consultants" were directly asked if they would write more Neurontin prescriptions as a result of the meeting. Such a question would have been irrelevant if the actual purpose of the meeting was to receive the "consultants'" advice. Parke-Davis also routinely tracked consultants' Neurontin prescription writing practices after these meetings. Using market data purchased from third parties, Parke-Davis analyzed whether the doctors they had paid had in fact written more Neurontin prescriptions after the meeting. Again, such data was only relevant if the real purpose of the payments was to influence the doctors to order more Neurontin.

151. A typical "consultants'" meeting was held in Jupiter Beach, Florida, for neurologists from Warner-Lamberts' Northeast Customer Business Unit during the weekend of April 19-21, 1996. The "consultants" selected for this meeting were not chosen on the basis of their consulting acumen, but because of their potential to write

Neurontin prescriptions. In a memorandum announcing the event to Parke-Davis's personnel, the Neurontin Marketing Team acknowledged that in order to target neurologists with the greatest potential for writing Neurontin prescriptions, sales personnel must select potential attendees from a list of the top prescription writers for antiepileptic drugs in the Northeast. Only persons who fell within this desirable demographic were to be invited.

152. Qualifying physicians were given a round-trip airfare to Florida (worth $800.00), two nights' accommodations (worth $340.00), free meals and entertainment, ground transportation and a "consultant's fee" of $250.00. Ample time was provided so that the Parke-Davis consultants could enjoy the beach resort. The value of attending the meeting was approximately $2,000.00 per physician.

153. The Jupiter Beach consultants' meeting included two half-days of presentations by Defendants relating to Neurontin, including extensive presentations relating to off-label uses. Technically, the Proworx division of Cline Davis produced the event; however, Defendants designed, monitored, and approved all aspects of the presentation. They selected the speakers, picked the presentation topics, and previewed the content of the presentations to make sure that they were acceptable. Parke-Davis paid all expenses relating to the consultants' meeting, including all payments to the attendees and the presenters, all travel, accommodation, meals and entertainment expenses, all presentation expenses, all expenses and fees incurred by Proworx, and the substantial fees paid to the participant physicians. Notwithstanding the FDA's prohibition regarding the provision of promotional materials relating to off-label uses, Parke-Davis provided

written abstracts of the presentations that detailed off-label use of Neurontin to each of their "consultants."

154. Defendants made no effort to obtain professional advice at Jupiter Beach from the "consultants" Defendants wined, dined, and entertained during the weekend. A followup memorandum to Parke-Davis's marketing officials noted that "the participants were delivered a hard-hitting message about Neurontin," and emphasized that the participants were encouraged to use Neurontin at higher doses. More importantly, after the conference Parke-Davis generated "trending worksheets" listing the doctors who attended the consultants' meeting. These worksheets enabled Defendants to track Neurontin prescription habits of the attendees before and after the consultant's meetings to determine if these "high writing" prescribers wrote more Neurontin prescriptions after the conference. Persuading these heavy prescribers to prescribe more Neurontin for their patients was, in fact, the sole purpose of the Jupiter Beach meeting.

155. Jupiter Beach was not unique. Defendants, in conjunction with the vendor participants, hosted many consultants' meetings in which the "consultants" received payments and gratuities, as well as presentations on off-label Neurontin use designed to change the physicians' prescription writing habits.

156. Not all payments to consultants were made at conferences as elaborate as Jupiter Beach. Many consultants' meetings consisted of lavish dinners at local restaurants. The emphasis on these meetings was also on off-label uses, and Parke-Davis paid $200 "honorariums" to the physicians who did nothing for the payment except show up. At none of the events did the consultants provide legitimate consultation to

Defendants, but at all of the events the "consultants" were encouraged to increase their Neurontin prescriptions.

2. Medical Education Seminars

157. Another format where Parke-Davis paid kickbacks to physicians to hear off-label promotion of Neurontin were programs billed as CME seminars. These conferences and seminars were set up to appear to qualify for the exception to the FDA's off-label rules that permitted physicians to learn about off-label uses of pharmaceuticals at independent seminars. However, these were not bona fide educational seminars. The reasons they were not bona fide are described in more detail above, but include the following: that Defendants designed and approved the programs; that Defendants handpicked the speakers; that Defendants approved the presentations; that Defendants selected the attendees based on their ability and willingness to prescribe high quantities of Neurontin; and Defendants monitored the prescribing patterns of the physicians who attended these conferences.

158. All of this was done to insure the purpose of the conference–to increase writing of Neurontin prescriptions–was achieved. Follow-up reports to marketing executives at Parke-Davis highlighted that the attendees received presentations regarding off-label marketing and recommendations for dosages larger than those labeled effective by the FDA. These memoranda also reported to senior executives the pledges made by attendees to order more Neurontin for their patients.

159. For some seminars, high prescription-writing physicians were selected to receive trips comparable to those Parke-Davis provided to the attendees of the Jupiter Beach consultants' meetings. Others were less lavish, but physicians still received free

tuition, free accommodations, free meals, and cash. Frequently Defendants' CME seminars were accredited by continuing medical education organizations, which meant that the physicians taking advantage of Defendants' "CME" meetings did not have to pay tuition or spend additional time to fulfill their continuing medical education licensure requirements by attending truly independent medical education programs.

3. Grants and "Studies"

160. Parke-Davis also made outright payments, in the form of supposed grants, to reward demonstrated Neurontin advocates. Parke-Davis's sales managers identified key doctors who actively prescribed Neurontin or programs that were willing to host Neurontin speakers and encouraged such persons or programs to obtain "educational grants" from them. Under this program of kickbacks Parke-Davis paid:

* $2,000.00 to Berge Ninmpolan, MD, "a great Neurontin believer," to attend a neurology seminar in San Francisco, in March 1996.

* $1,000.00 to the University of Texas at Houston Department of Neurology to host a symposium where presentations would be made regarding successful off-label treatment with Neurontin.

* $3,000.00 to the University of Texas Medical School to host a conference in August 1996 at which a well-known specialist in epilepsy, who prescribed Neurontin, would attend.

* $4,000.00 to pay for a neurologist from the University of Texas at San Antonio to attend the American Epilepsy Society Conference in December 1996, a conference at which Parke-Davis was presenting extensive documentation on off-label uses for Neurontin.

* $2,500.00 to the University of Texas in Houston to bring Dr. B.J. Wilder to the campus to hold a seminar. Dr. Wilder was one of Neurontin's biggest boosters for off-label indications and had been paid tens of thousands of dollars to promote Neurontin's off-label uses for Parke-Davis across the country.

* $2,500.00 in June 1996 to pay for representatives from the University of Pennsylvania Medical Center to attend a conference in Saint Petersburg, Russia on the utilization of anti-epileptic drugs, including Neurontin.

* $5,000.00 in December 1996 to Dr. Alan B. Ettinger, of Stonybrook, N.Y., a physician who had informed Parke-Davis that he was interested in possibly doing research in Neurontin and maintained a database of patients who were treated with Neurontin.

* $500 to Bruce Ehrenberg, of Boston, MA, a leading speaker for Parke-Davis regarding off-label use of Neurontin, to attend a conference in China.

* $1000 to Israel Abrams, M.D., Paul C. Marshall, M.D., Beth Rosten, M.D. and Spencer G. Weig, of Worcester MA, for educational programs in February 1996. According to the local Parke Davis representative requesting the grant, "much of the Neurontin success in Worcester has been attributed to . . . the 4 pedi[atric] epileptologists below."

* $1,400 to Dr. Ahmad Beydoun of Ann Arbor, MI for post-graduate training in March 1996. This grant was processed on a quick turnaround, the Parke-Davis representative noting "I realize that this is a very short time line; however, Dr. Beydoun is a very important customer."

* $1,500 to Jim McAuley, R.Ph, Ph.D. for educational materials relating to epilepsy. Parke-Davis decided to provide the funds because McAuley was an advocate of Neurontin and he was important in getting another Parke-Davis drug, Cerebyx, accepted on the formulary for Ohio State University.

* A grant in an unknown amount to University Hospital in Cleveland in exchange for hosting programs regarding Neurontin's use in treating neuropathic pain at conferences specifically devoted to obtaining referrals from other doctors.

161. These grants, and others, were charged to the Neurontin marketing budget. Each of these grants were made solely because an individual receiving the money was a large Neurontin supporter or was going to host a program where a well known Neurontin supporter would recommend that other physicians increase their prescriptions of Neurontin. Each of these grant awards constituted a reward or kickback for the recipient's advocacy of Neurontin.

162. Parke-Davis's medical liaisons informed leading Neurontin prescribers that significant advocacy for Neurontin would result in the payment of large grants. These studies did not involve significant work for the physicians. Often they required little more than collating and summarizing office notes or records. Often the physicians contributed nothing at all to the study because Parke-Davis frequently hired technical writers to write the articles for which the "authors" had been given grants.

163. Defendants were aware that these articles and studies provided minimal scientific benefit. In a letter to the FDA in June 1997, Parke-Davis submitted a list of "studies relating to pain, pain syndromes, and psychiatric disorders" but failed to include any of the studies described below. Parke-Davis intentionally neglected to report these "studies" to the FDA because they knew the funded "research" had no scientific value and would not be deemed a scientific trial by the FDA. Payments Parke-Davis made for these "studies" included $7,000.00 to Longmire for "Neurontin For Pain Reduction of Sympathetically Medicated Pain and Sudomotor Function," and $2,000.000 to Longmire for "Retrospective Analysis of Neurontin in the Treatment of Pain." Other payments included, but were not limited to, the following:

* Statistical Analysis of Patients Treated With Hans Hansen, M.D., Statesville, N.C.; $7,000.00

* Data entry for Neurontin and Pain Analysis David Meyer, M.D. [amount unknown] Trial of Neurontin for distal symmetric polyneuropathy associated with AIDS; Joseph Weissman, M.D., Atlanta, GA; $20,000.00

* Neurontin for neuropathic pain in chronic pain syndromes; Lavern Brett, M.D., Washington, D.C.; $25,000.00

* Retrospective chart analysis of Neurontin use with bipolar disorder patients; Ralph S. Rybeck, M.D.; $5,000.00

* Retrospective Analysis of Neurontin in the treatment of chronic pain; Don Schanz, D.O.; Traverse City, MI; $8,000.00

* Case histories relating to use of Neurontin as an adjuvant analgesic Elizabeth J. Narcessian, M.D.; W. Orange, N.J.; $4,000.00

164. Plaintiffs do not believe these are the only such payments made. One particularly large study conducted by Parke-Davis served as yet another engine to reward physicians financially for prescribing Neurontin. In 1995 and 1996 Parke-Davis conducted an enormous Phase IV trial known as STEPS. Although STEPS took the form of a research clinical trial, it was, in fact, a marketing ploy designed to induce neurologists to become comfortable prescribing Neurontin at a far higher dose than indicated in the FDA approved labeling. While most clinical studies have a limited number of investigators treating a number of patients qualified for the study, the STEPS protocol called for over 1,200 "investigators" to enroll only a few patients each. The participating physicians were instructed to titrate their patients to higher-than-labeled dosages of Neurontin to demonstrate that patients could tolerate high dosages of the drug. Rewarding physicians for prescribing high doses of Neurontin was another way to increase Neurontin sales, as higher per-patient dosages increased the amount of Neurontin sold. Additionally, the STEPS study was also designed to induce physicians to place non-study patients on Neurontin on doses higher than those found effective in the clinical trials monitored by the FDA.

165. Physicians enrolling in the STEPS study were paid for agreeing to participate in the study and for every patient enrolled. At the conclusion of the study, Parke-Davis offered each of the 1,200 investigators additional cash for each patient the doctor kept on Neurontin after the study ended. These payments constituted kickbacks,

since each participating doctor was expressly paid for writing Neurontin prescriptions for their patients and the payment was offered expressly to change the physicians' behavior.

H. Illegal Off-Label Promotion Has Continued As Has The Continuing Impact Of The Earlier Misconduct

166. As a result of the conduct described above, physicians received large amounts of false information and therefore continue to prescribe Neurontin for off-label uses for which there is no reliable scientific support, and for which it is not effective or medically necessary.

167. A July 1, 2002, letter from Dr. Lisa Stockbridge of the Department of Health & Human Services ("HHS") confirms that Defendants continued as of May 2002 to engage in off-label promotional efforts. Dr. Stockbridge notified Pfizer that certain of its marketing practices are "in violation of the Federal Food, Drug and Cosmetic Act . . . because [Pfizer] makes representations about Neurontin that are false and misleading." In particular, HHS determined that Pfizer marketing materials suggested that the mechanism of action of Neurontin had been established when it was not appropriate to make such a claim, and that materials suggested that Neurontin could be used as monotherapy when it was only appropriate to indicate Neurontin as adjunctive therapy in the treatment of partial seizures. The Stockbridge letter determined that Pfizer's marketing materials were misleading and ordered immediate discontinuation of their use. The marketing practices found to be misleading by HHS are consistent with those routinely engaged in through the Off-Label Promotion Scheme under Parke-Davis's direction.

V. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
VIOLATION OF THE ALABAMA DECEPTIVE TRADE PRACTICES ACT
(Ala. Code § 8-19-1, *et seq.*)
(Against All Defendants)

170. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

171. The Alabama Deceptive Trade Practices Act ("ADTPA"), Ala. Code §8-19-5 (1975), prohibits:

* Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have or that a person has sponsorship, approval, status, affiliation, or connection that he or she does not have;

* Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

* Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services; and

* Engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

172. As alleged herein, Defendants violated such sections of the ADTPA.

173. Defendants' commission of these acts or practices declared unlawful under the ADTPA caused monetary damage to consumers, as well as to Plaintiffs, in that both consumers and Plaintiffs were caused to pay for Neurontin when it was not medically necessary or effective for the condition for which it was prescribed. This action, which is to recover damages, but which will also deter Defendants from engaging in similar conduct in the future, will have the effect of protecting the interests of both the consuming public and legitimate businesspersons in Alabama.

174. Pursuant to Ala. Code §8-19-10 (1975), Plaintiffs have a private right of action for violations of the ADTPA to recover any actual damages sustained by them, and to recover other amounts allowed by the ADTPA.

175. As a proximate cause of the violations of the ADTPA, Plaintiffs have been damaged and injured.

176. To the extent it is applicable, Plaintiffs have complied with Ala. Code § 8-19-10(e), having provided a written demand for relief to Defendants at least 15 days prior to the filing of this action. Defendants have made no written tender of settlement.

WHEREFORE, PREMISES CONSIDERED, Plaintiffs seek from Defendants the amount of actual damages sustained by them, treble damages, costs and attorneys' fees, and any other damages or relief allowed by law.

SECOND CLAIM FOR RELIEF
UNJUST ENRICHMENT
(Against Pfizer, Warner-Lambert, and Fictitious Defendants A-ZZZ)

177. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

178. As the intended and expected result of their wrongdoing as set forth in this Complaint, Defendants have profited and benefited from payments made by Plaintiffs for Neurontin.

179. In exchange for the payments made for Neurontin, and at the time the payments were made, Plaintiffs expected that the drug was a safe, medically effective and necessary treatment for the condition, illness, disease, disorder or symptom for which it was prescribed by a physician.

fraudulently failed to disclose the existence and/or the true

concealing or suppressing, and causing others to conceal or suppress, information about the true safety and efficacy of Neurontin which allowed the drug to be prescribed for reasons not approved by the FDA; and (e) actively concealing or suppressing, and causing others to conceal or suppress, information about the results of scientific studies or negative clinical evidence.

184. Defendants knew at the time that they made these misrepresentations that such were false or that Defendants had failed to disclose facts they were under an obligation to disclose, and willfully deceived Plaintiffs to act to their detriment.

185. Defendants were aware and intended that Plaintiffs would reasonably rely on these misrepresentations or omissions, and that such representations or omissions were material in Plaintiffs' decision to pay for Neurontin. Defendants contemplated, therefore, that Plaintiffs would be induced by reasonably relying on Defendants misrepresentations and omissions to act to Plaintiffs' detriment.

186. Defendants were under a duty to disclose the material facts alleged herein to have been omitted and/or suppressed, particularly where Defendants had knowledge superior to Plaintiffs of said material facts.

187. Defendants intended to deceive Plaintiffs by their misrepresentations, omissions, and active concealment of material facts, as alleged herein.

188. Plaintiffs reasonably relied upon Defendants' numerous misrepresentations and omissions of material fact. Plaintiffs had no reason to doubt the scientific validity of the information Defendants promoted through their marketing and sales strategies.

189. Defendants' misrepresentations and omissions of material fact directly and proximately caused Plaintiffs' damages.

WHEREFORE, PREMISES CONSIDERED, Plaintiffs seek from Defendants an amount of compensatory and punitive damages as assigned by a jury, costs and attorneys' fees, and any other damages or relief allowed by law.

FOURTH CLAIM FOR RELIEF
NEGLIGENT OR WANTON CONDUCT
(Against All Defendants)

190. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

191. Defendants engaged in negligent or wanton conduct in that they:

a. misrepresented the efficacy and scientific studies related to Neurontin;

b. failed to disclose existing negative clinical evidence;

c. advertised and marketed the drug as being efficacious for off-label purposes with no clinical support;

d. provided misleading and false information to physicians to induce them to prescribe Neurontin for off-label uses; and

e. committed all other acts and/or omissions alleged herein.

192. Defendants were under a duty to act reasonably under the circumstances alleged herein, and breached that duty by the actions and omissions alleged herein.

193. Defendants acted intentionally, willfully and consciously in committing the acts and/or omissions alleged herein.

194. As a proximate consequence of said conduct, Plaintiffs have been caused to suffer injury and damages.

WHEREFORE, PREMISES CONSIDERED, Plaintiffs request from Defendants an amount of compensatory and punitive damages as assigned by a jury, costs and attorneys' fees, and any other damages or relief allowed by law.

FIFTH CLAIM FOR RELIEF
NEGLIGENCE OR WANTONNESS PER SE
(Against All Defendants)

195. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

196. The FDCA and regulations promulgated thereunder with respect to the marketing of drugs for off-label uses were enacted or promulgated to protect a class of persons that includes Plaintiffs. One of the purposes of the FDCA and related regulations is to insure that physicians are provided with accurate information about the drugs they prescribe, so that patients are prescribed drugs that are medically effective and necessary, and so that third-party payers, such as Plaintiffs, may presume that drugs for which they provide payment are medically effective and necessary.

197. The injuries Plaintiffs complain of herein are of the type contemplated by the FDCA and regulations promulgated thereunder.

198. Defendants have violated the FDCA and related regulations by committing the acts and/or omissions alleged herein. Indeed, Defendant Warner-Lambert has pled guilty to violating the FDCA and related regulations.

199. Defendants are therefore guilty of negligence as a matter of law.

200. Defendants acted intentionally, willfully and consciously in violating the FDCA and related regulations, and are therefore also guilty of wantonness as a matter of law.

201. Defendants' violation of the FDA and related regulations proximately caused Plaintiffs injury and damages.

WHEREFORE, PREMISES CONSIDERED, Plaintiffs request from Defendants an amount of compensatory and punitive damages as assigned by a jury, costs and attorneys' fees, and any other damages or relief allowed by law.

SIXTH CLAIM FOR RELIEF
CONSPIRACY
(Against All Defendants)

202. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

203. Defendants conspired and/or combined with one another and/or with unknown third parties to accomplish the unlawful acts alleged herein, and/or to accomplish lawful ends by unlawful means, which acts and/or means included, but are not limited to, providing false, misleading, incomplete and inaccurate information related to the efficacy and FDA-approved uses of Neurontin as herein alleged.

204. As a proximate consequence of said conspiracy and collusion among the named Defendants and/or among the named Defendants and unknown third parties, the Plaintiffs have been injured and damaged.

WHEREFORE, PREMISES CONSIDERED, Plaintiffs request from Defendants an amount of compensatory and punitive damages as assigned by a jury, costs and attorneys' fees, and any other damages or relief allowed by law.

PLAINTIFFS DEMAND A TRIAL BY STRUCK JURY AS TO ALL CLAIMS ASSERTED HEREIN AND ALLOWABLE BY LAW.

Respectfully Submitted By:

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Plaintiffs' addresses are as follows:

Blue Cross and Blue Shield of Alabama
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Birmingham, Alabama 35244

Municipal Workers Compensation Fund, Inc.
535 Adams Avenue
Montgomery, Alabama 36104

PLEASE SERVE DEFENDANTS VIA THE FOLLOWING MEANS AS FOLLOWS:

By Certified Mail, Return Receipt Requested:

Pfizer, Inc.
c/o The Corporation Company
2000 Interstate Park Drive, Suite 204
Montgomery, Alabama 36109

Warner-Lambert Company LLC
c/o The Corporation Company
2000 Interstate Park Drive, Suite 204
Montgomery, Alabama 36109

Warner-Lambert Company
235 East 42nd Street
New York, New York 10017

Parke-Davis, a Division of Warner Lambert Company LLC and Warner Lambert Company
235 East 42nd Street
New York, New York 10017

By Certified Mail, Return Receipt Requested, Restricted Delivery:

David B. Longmire, M.D.
13150 Highway 43
Russellville, Alabama 35653-4558

PURSUANT TO ALA. CODE § 8-19-10(d), PLEASE ALSO MAIL A COPY OF THIS COMPLAINT TO:

Troy King, Attorney General
Office of the Attorney General
Alabama State House
11 South Union Street, Third Floor
Montgomery, AL 36130

and

Ellen Brooks, District Attorney
Office of the District Attorney of Montgomery County, Alabama
P.O. Box 1667
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